

US3432580 (Prod: Brigham and Womens Hospital)

Generated By: KC Joubran

Generated On: 11 Aug 2021 22:42:38

All time stamps listed in this document are displayed in GMT

US3432580

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

Participant ID

US3432580

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

US3432580

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

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

Visit date (dd MMM yyyy)	01 OCT 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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US3432580

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

Date of Birth (MMM yyyy)	(b) (6) 1977
Age	43
Age Units	YEARS
Age (Derived)	43
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
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

US3432580

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

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

US3432580

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3432580

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

Were any significant conditions reported?

Yes ☒

No ☐

US3432580

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

Condition	ASTHMA (MILD)
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

US3432580

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

Condition	HTN
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3432580

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

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

US3432580

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

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

US3432580

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

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

US3432580

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

Condition	ECZEMA (RIGHT MIDDLE DIGIT)
Start date (dd MMM yyyy)	UN MAR 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	MAR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3432580

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

Condition	ENVIRONMENTAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	
Stop Year (derived)	

US3432580

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	1 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	10:49 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 10:49
Height (<i>xxx.x</i>)	158.5 cm
Weight (<i>xxx.x</i>)	74.6 kg
BMI (<i>xxx.x</i>)	29.69479 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432580

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

1 OCT 2020

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

US3432580

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

Date of assessment (dd MMM yyyy) 1 OCT 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

If Partner medically sterile or Other, specify _____
If Surgically sterile, date of surgery (dd MMM yyyy) _____
Date of surgery unknown False
If Post-menopausal, date of last menstruation (dd MMM yyyy) _____
Date of last menstruation unknown False

US3432580

Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	01 OCT 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3432580

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

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

US3432580

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

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)	True
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	False
Specify	

US3432580

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

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

US3432580

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

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

What was the participant's randomization number? 116145

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

Height	ND - Not Done
Weight	ND - Not Done

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

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)	1 OCT 2020
Time of assessment (00:00-23:59)	10:49 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 10:49
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

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)	1 OCT 2020
Time of assessment (00:00-23:59)	12:54 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 12:54
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3432580

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

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.

US3432580

Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

US3432580

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 1 OCT 2020

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

Treatment Date and Time (derived) 1 OCT 2020 12:23

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

What was the frequency of the study treatment dosing? ONCE

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

US3432580

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 OCT 2020
Collection time (00:00-23:59)	11:20 (24 HR)
Collection date and time (derived)	1 OCT 2020 11:20

US3432580

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

Collection date (dd MMM yyyy)			1 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:35	1 OCT 2020 11:35
Nasopharyngeal Swab 2	No		

US3432580

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 12:55

PC Open Date & Time

01 OCT 2020 12:43

PC Close Date & Time

01 OCT 2020 15:13

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.7 °F

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

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

PC Time Stamp	02 OCT 2020 03:53
PC Open Date & Time	01 OCT 2020 16:08
PC Close Date & Time	02 OCT 2020 11:59

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 12:35

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:42:38

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 14:29

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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

04 OCT 2020 23:31

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 17:48

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:42:38

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

06 OCT 2020 19:52

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 OCT 2020 22:15

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 12:56

PC Open Date & Time

01 OCT 2020 12:43

PC Close Date & Time

01 OCT 2020 15:13

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

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

02 OCT 2020 03:54

PC Open Date & Time

01 OCT 2020 16:08

PC Close Date & Time

02 OCT 2020 11:59

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 12:36

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 OCT 2020 14:27

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 23:31

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 OCT 2020 17:48

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 OCT 2020 19:52

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 OCT 2020 22:14

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

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 ☐

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

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

No ☒

Yes ☐

PC Time stamp	01 OCT 2020 12:56
PC Open Date & Time	01 OCT 2020 12:43
PC Close Date & Time	01 OCT 2020 15:13

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

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 ☐

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

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

No ☒

Yes ☐

PC Time stamp	02 OCT 2020 03:54
PC Open Date & Time	01 OCT 2020 16:08
PC Close Date & Time	02 OCT 2020 11:59

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:42:38

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 ☒

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:42:38

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 12:37
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

53 of 1822

EAB) (1725)

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:42:38

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 14:28
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:42:38

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 ☒

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:42:38

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 23:31
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:42:38

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 ☒

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:42:38

		Yes <input type="checkbox"/>
PC Time stamp	05 OCT 2020 17:48	
PC Open Date & Time	05 OCT 2020 12:00	
PC Close Date & Time	06 OCT 2020 11:59	

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:42:38

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 ☒

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:42:38

Yes <input type="checkbox"/>	
PC Time stamp	06 OCT 2020 19:53
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:42:38

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

61 of 1822

EAB) (1725)

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:42:38

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 22:14
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3432580

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432580

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432580

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

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

US3432580

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432580

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432580

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432580

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

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

Visit date (dd MMM yyyy)	5 NOV 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	VISIT2
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US3432580

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

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)	5 NOV 2020
Time of assessment (00:00-23:59)	12:23 (24 HR)
Vital Signs Date and Time (derived)	5 NOV 2020 12:23
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	076 mmHg
Diastolic Blood Pressure units	MMHG

US3432580

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

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)	5 NOV 2020
Time of assessment (00:00-23:59)	13:51 (24 HR)
Vital Signs Date and Time (derived)	5 NOV 2020 13:51
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 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

US3432580

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 NOV 2020

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

US3432580

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 5 NOV 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

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

US3432580

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

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) 5 NOV 2020

What was the treatment time? (00:00-23:59) 13:20 (24 HR)

Treatment Date and Time (derived) 5 NOV 2020 13:20

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

US3432580

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

5 NOV 2020

Collection time (00:00-23:59)

13:06 (24 HR)

Collection date and time (derived)

5 NOV 2020 13:06

US3432580

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

Collection date (dd MMM yyyy)			5 NOV 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:09	5 NOV 2020 13:09
Nasopharyngeal Swab 2	No		

US3432580

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 NOV 2020 13:50

PC Open Date & Time

05 NOV 2020 13:40

PC Close Date & Time

05 NOV 2020 16:10

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

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

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 05 NOV 2020 17:05

PC Close Date & Time 06 NOV 2020 11:59

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:42:38

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

99.2 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

06 NOV 2020 12:03

PC Open Date & Time

06 NOV 2020 12:00

PC Close Date & Time

07 NOV 2020 11:59

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:42:38

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

98.1 °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

07 NOV 2020 22:31

PC Open Date & Time

07 NOV 2020 12:00

PC Close Date & Time

08 NOV 2020 11:59

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 NOV 2020 06:34

PC Open Date & Time

08 NOV 2020 12:00

PC Close Date & Time

09 NOV 2020 11:59

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 NOV 2020 00:01

PC Open Date & Time

09 NOV 2020 12:00

PC Close Date & Time

10 NOV 2020 11:59

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 NOV 2020 09:44

PC Open Date & Time

10 NOV 2020 12:00

PC Close Date & Time

11 NOV 2020 11:59

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 NOV 2020 00:00

PC Open Date & Time

11 NOV 2020 12:00

PC Close Date & Time

12 NOV 2020 11:59

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 NOV 2020 13:50

PC Open Date & Time

05 NOV 2020 13:40

PC Close Date & Time

05 NOV 2020 16:10

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

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

05 NOV 2020 17:40

PC Open Date & Time

05 NOV 2020 17:05

PC Close Date & Time

06 NOV 2020 11:59

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:42:38

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

06 NOV 2020 12:02

PC Open Date & Time

06 NOV 2020 12:00

PC Close Date & Time

07 NOV 2020 11:59

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:42:38

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

07 NOV 2020 22:30

PC Open Date & Time

07 NOV 2020 12:00

PC Close Date & Time

08 NOV 2020 11:59

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:42:38

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

09 NOV 2020 06:33

PC Open Date & Time

08 NOV 2020 12:00

PC Close Date & Time

09 NOV 2020 11:59

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:42:38

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

10 NOV 2020 00:00

PC Open Date & Time

09 NOV 2020 12:00

PC Close Date & Time

10 NOV 2020 11:59

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:42:38

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

11 NOV 2020 09:44

PC Open Date & Time

10 NOV 2020 12:00

PC Close Date & Time

11 NOV 2020 11:59

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:42:38

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

11 NOV 2020 23:59

PC Open Date & Time

11 NOV 2020 12:00

PC Close Date & Time

12 NOV 2020 11:59

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

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 ☐

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

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

No ☒

Yes ☐

PC Time stamp	05 NOV 2020 13:51
PC Open Date & Time	05 NOV 2020 13:40
PC Close Date & Time	05 NOV 2020 16:10

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

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 ☐

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

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

No ☒

Yes ☐

PC Time stamp	05 NOV 2020 17:41
PC Open Date & Time	05 NOV 2020 17:05
PC Close Date & Time	06 NOV 2020 11:59

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:42:38

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 ☒

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:42:38

Yes <input type="checkbox"/>	
PC Time stamp	06 NOV 2020 12:02
PC Open Date & Time	06 NOV 2020 12:00
PC Close Date & Time	07 NOV 2020 11:59

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

100 of 1822

EAB) (1725)

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:42:38

Yes <input type="checkbox"/>	
PC Time stamp	07 NOV 2020 22:30
PC Open Date & Time	07 NOV 2020 12:00
PC Close Date & Time	08 NOV 2020 11:59

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:42:38

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

102 of 1822

EAB) (1725)

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:42:38

Yes <input type="checkbox"/>	
PC Time stamp	09 NOV 2020 06:33
PC Open Date & Time	08 NOV 2020 12:00
PC Close Date & Time	09 NOV 2020 11:59

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:42:38

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 ☒

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:42:38

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

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

106 of 1822

EAB) (1725)

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:42:38

Yes <input type="checkbox"/>	
PC Time stamp	11 NOV 2020 09:44
PC Open Date & Time	10 NOV 2020 12:00
PC Close Date & Time	11 NOV 2020 11:59

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:42:38

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 ☒

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:42:38

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

US3432580

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432580

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432580

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3432580

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432580

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432580

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432580

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3432580

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	3 DEC 2020
Time of assessment (00:00-23:59)	12:23 (24 HR)
Vital Signs Date and Time (derived)	3 DEC 2020 12:23
Temperature (xxx.x)	96.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	INFRARED
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432580

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

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.

US3432580

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

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

Collection date (dd MMM yyyy)	3 DEC 2020
-------------------------------	------------

Collection time (00:00-23:59)	12:32 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	3 DEC 2020 12:32
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US3432580

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

DAY 61

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 DEC 2020 06:14:44

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 DEC 2020 12:00:43
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 DEC 2020 07:21:51
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 DEC 2020 12:12:31
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

26 DEC 2020 00:02:45

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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	05 JAN 2021 18:04:14
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

11 JAN 2021 12:00:30

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 JAN 2021 12:06:46

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

25 JAN 2021 12:01:25

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 JAN 2021 00:01:29
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 FEB 2021 17:59:40

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 FEB 2021 17:18:53

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 FEB 2021 17:00:35

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

02 MAR 2021 17:59:19

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 12:00:39

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

15 MAR 2021 15:04:24

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 MAR 2021 12:00:25

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 MAR 2021 13:20:31
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 APR 2021 17:59:27

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 11:37:18

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

20 APR 2021 17:59:26

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

26 APR 2021 12:00:31

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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 <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	02 MAY 2021 12:46:42
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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 <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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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 <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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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 <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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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="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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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 <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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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 <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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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 <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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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 ☐

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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 ☐

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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 <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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

DAY 362

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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 <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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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 <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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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 <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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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°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 ☐

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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 ☐

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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 ☐

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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 <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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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 ☐

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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 <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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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 <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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

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23 FEB 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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 ☐

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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 ☐

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

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09 MAR 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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 <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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

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12 MAR 2022 00:01

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16 MAR 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

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19 MAR 2022 00:01

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23 MAR 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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 <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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

02 APR 2022 00:01

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06 APR 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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 ☐

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

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13 APR 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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 ☐

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

16 APR 2022 00:01

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20 APR 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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 ☐

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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 <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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

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07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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 <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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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="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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

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15 JUN 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

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22 JUN 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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 ☐

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

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29 JUN 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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 <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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

02 JUL 2022 00:01

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06 JUL 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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 ☐

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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 ☐

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

Patient Cloud Open Date & Time	13 AUG 2022 00:01
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Patient Cloud Close Date & Time	17 AUG 2022 23:59
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US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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="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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

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24 AUG 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

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31 AUG 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

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03 SEP 2022 00:01

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07 SEP 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

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14 SEP 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

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21 SEP 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

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28 SEP 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

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12 OCT 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Open Date & Time](#)

15 OCT 2022 00:01

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19 OCT 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Open Date & Time](#)

22 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Close Date & Time](#)

09 NOV 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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 <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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Open Date & Time](#)

12 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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 <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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Open Date & Time](#)

19 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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 <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"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Close Date & Time](#)

30 NOV 2022 23:59

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

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

[Patient Cloud Open Date & Time](#)

03 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2022 23:59

US3432580

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 11 Aug 2021 22:42:38

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		02 MAR 2021 17:59:28

US3432580

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3432580

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:25:04

Generated On: 11 Aug 2021 22:42:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432580

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432580

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432580

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 21:20:44

Generated On: 11 Aug 2021 22:42:38

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3432580

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 21:20:44

Generated On: 11 Aug 2021 22:42:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432580

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 21:20:44

Generated On: 11 Aug 2021 22:42:38

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432580

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 21:20:44

Generated On: 11 Aug 2021 22:42:38

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432580

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:42:38

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID _____

US3432580

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

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

US3432580

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:42:38

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.

US3432580

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:42:38

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

US3432580

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:42:38

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3432580

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Aug 2021 22:42:38

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

US3432580

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 11 Aug 2021 22:42:38

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3432580

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

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

Visit date (dd MMM yyyy)	19 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3432580

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

Form: Unblinding

Data signed: (b) (4) 25 Apr 2021 11:27:57

Generated On: 11 Aug 2021 22:42:38

Date of updated informed consent (dd MMM yyyy) 19 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 19 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3432580

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 JAN 2021

Collection time (00:00-23:59)

14:25 (24 HR)

Collection date and time (derived)

19 JAN 2021 14:25

US3432580

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 JAN 2021

Collection time (00:00 - 23:59)

14:30

Collection Date and Time (derived)

19 JAN 2021 14:30

US3432580

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 04 Apr 2021 21:20:44

Generated On: 11 Aug 2021 22:42:38

Did the participant experience any adverse events?

Yes ☐

No ☒

If Yes, enter details on the Adverse Events form.

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

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

Yes ☒

No ☐

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

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

332 of 1822

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" 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 1980	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
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"/>

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HTN

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

334 of 1822

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

	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 2008	
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"/>

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HTN

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

336 of 1822

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2008	
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"/>

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

Name of Medication WELLBUTIN

Prophylaxis Yes ☐
No ☒

Indication DEPRESSION

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
EAB) (1725)

338 of 1822

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

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

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

Name of Medication TEMAZEPAM

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

340 of 1822

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

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

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GERD

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

342 of 1822

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

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

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

Name of Medication BETAMETHASONE,
AUGMENTED 0.05 % TOPICAL
CREAM

Prophylaxis Yes ☐
No ☒

Indication ECZEMA

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☒
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

344 of 1822

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

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

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication HEADACHES AND MUSCLE
ACHES

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

346 of 1822

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

	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)	6 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)		6 NOV 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input 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"/>

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

Name of Medication BIOTIN + KERATIN

Prophylaxis Yes ☐
No ☒

Indication HAIR GROWTH

Dose per administration 10,000/100

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

If dose unit is Other, specify UG/MG

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

348 of 1822

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	31 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH
(PROPHYLAXIS)

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

350 of 1822

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

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

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

Name of Medication BIOTIN

Prophylaxis Yes ☐
No ☒

Indication HAIR GROWTH

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

352 of 1822

EAB) (1725)

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

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

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

Name of Medication ZYTERC CETRIZINE

Prophylaxis Yes ☐
No ☒

Indication ENVIRONMENTAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

354 of 1822

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 19 Feb 2021 03:24:48

Generated On: 11 Aug 2021 22:42:38

	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 2006	
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"/>

US3432580

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 04 Apr 2021 21:20:44

Generated On: 11 Aug 2021 22:42:38

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3432580

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Aug 2021 22:42:38

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

US3432580

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Aug 2021 22:42:38

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

Audit

US3432580 (Prod: Brigham and Womens Hospital)

US3432580

Form: Participant Creation

Generated On: 11 Aug 2021 22:42:38

[Participant ID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 02:15:46
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
User entered 'US3432580'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Oct 2020 14:58:07

US3432580

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:42:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:47:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 20:31:52

US3432580

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:47:54
User entered '01 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Oct 2020 14:58:09

US3432580

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:42:38

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:47:54
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	01 Oct 2020 20:31:52

US3432580

Folder: Screening

Form: Visit Date

Generated On: 11 Aug 2021 22:42:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered 'SCRN'	System	01 Oct 2020 20:31:52

US3432580

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:42:38

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:48:01
User entered (b) (6) 1977'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Oct 2020 14:58:10

US3432580

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:42:38

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:48:02
User entered '43'	(b) (4), (b) (6)	01 Oct 2020 20:30:30

US3432580

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:42:38

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered 'YEARS'	System	01 Oct 2020 20:30:30

US3432580

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:42:38

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered '43'	System	01 Oct 2020 16:45:26

US3432580

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:42:38

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 01:01:06
User closed query 'Please update Child bearing potential and pregnancy page.' (Site from CRA).	(b) (4), (b) (6)	02 Dec 2020 01:01:05
User entered 'Female (F)' reason for change: Per Query Resolution	Alexander Mills (b) (4)	23 Nov 2020 21:02:51
Query 'Please update Child bearing potential and pregnancy page.' answered by data change (Site from CRA).	System	23 Nov 2020 21:02:45
User entered 'Male (M)' reason for change: Data Entry Error	Alexander Mills (b) (4)	23 Nov 2020 21:02:45
Comment added 'I updated the childbearing potential etc.'.	(b) (4), (b) (6)	12 Nov 2020 21:29:51
User opened query 'Please update Child bearing potential and pregnancy page.' (Site from CRA).	(b) (4), (b) (6)	24 Oct 2020 11:43:43
User closed query 'Please complete the pregnancy test and child bearing potential in EDC once it populates.' (Site from CRA).	(b) (4), (b) (6)	24 Oct 2020 11:42:27
User closed query 'Per source sex is female, please verify.' (Site from CRA).	(b) (4), (b) (6)	24 Oct 2020 11:42:22
Query 'Please complete the pregnancy test and child bearing potential in EDC once it populates.' answered by data change (Site from CRA).	System	22 Oct 2020 16:28:22
Query 'Per source sex is female, please verify.' answered by data change (Site from CRA).	System	22 Oct 2020 16:28:22
User entered 'Female (F)' reason for change: Data Entry Error	Julia Klopfer (b) (4)	22 Oct 2020 16:28:22
User opened query 'Please complete the pregnancy test and child bearing potential in EDC once it populates.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 16:25:42
User opened query 'Per source sex is female, please verify.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:46:25
Query 'Per source gender is female please verify.' canceled (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:45:54
User opened query 'Per source gender is female please verify.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:44:09

US3432580

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:42:38

Sex

Audit	User	Time (GMT)
User entered 'Male (M)'	(b) (4), (b) (6)	01 Oct 2020 20:30:30

US3432580

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:42:38

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:34:38
User closed query 'Per source ethnicity is Non-Hispanic/Latino please verify.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 19:34:37
Query 'Per source ethnicity is Non-Hispanic/Latino please verify.' answered by data change (Site from CRA).	System	11 Nov 2020 16:36:29
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)' reason for change: Data Entry Error	Jun Bai Park Chang (b) (4)	11 Nov 2020 16:36:29
User opened query 'Per source ethnicity is Non-Hispanic/Latino please verify.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:45:50
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4), (b) (6)	01 Oct 2020 20:30:30

US3432580

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:42:38

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:48:06
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 20:30:30

US3432580

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:42:38

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:48:08
User entered 'I'	(b) (4), (b) (6)	01 Oct 2020 20:30:30

US3432580

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:42:38

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:48:10
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 20:30:30

US3432580

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:42:38

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:48:11
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 20:30:30

US3432580

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:42:38

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:48:13
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 20:30:30

US3432580

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:42:38

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:48:15
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 20:30:30

US3432580

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:42:38

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:48:17
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:30:30

US3432580

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:42:38

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:48:18
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 20:30:30

US3432580

Folder: Screening

Form: Demographics

Generated On: 11 Aug 2021 22:42:38

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:48:21
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 20:30:30

US3432580

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:42:38

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:56:06
User entered '1 Oct 2020'	Phoebe Cunningham (b) (4)	01 Oct 2020 16:45:26

US3432580

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered 'Oct 2020'	System	01 Oct 2020 16:45:26

US3432580

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered '2020'	System	01 Oct 2020 16:45:26

US3432580

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:42:38

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 14:27:26
User closed query 'Email for Amendment 4 released in the afternoon after 2:00pm, so subject will still be under amendment 3 please correct.' (Site from CRA).	(b) (4), (b) (6)	24 Oct 2020 11:43:52
Query 'Email for Amendment 4 released in the afternoon after 2:00pm, so subject will still be under amendment 3 please correct.' answered by data change (Site from CRA).	System	22 Oct 2020 16:28:44
User entered 'Amendment 3 (3)' reason for change: Data Entry Error	Julia Klopfer (b) (4)	22 Oct 2020 16:28:44
User opened query 'Email for Amendment 4 released in the afternoon after 2:00pm, so subject will still be under amendment 3 please correct.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:56:00
User entered 'Amendment 4 (4)'	Phoebe Cunningham (b) (4)	01 Oct 2020 16:45:26

US3432580

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:56:11
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	01 Oct 2020 16:45:26

US3432580

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:42:38

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:56:12
User entered empty.	Phoebe Cunningham (b) (4)	01 Oct 2020 16:45:26

US3432580

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:42:38

[If reason for screen fail is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:56:15
User entered empty.	Phoebe Cunningham (b) (4)	01 Oct 2020 16:45:26

US3432580

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:42:38

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:56:17
User entered 'No (N)'	Phoebe Cunningham (b) (4)	01 Oct 2020 16:45:26

US3432580

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:42:38

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:56:18
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	01 Oct 2020 14:58:09

US3432580

Folder: Screening

Form: Enrollment

Generated On: 11 Aug 2021 22:42:38

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered 'I'	System	01 Oct 2020 16:45:29

US3432580

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:24
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	01 Oct 2020 16:45:29

US3432580

Folder: Screening

Form: Medical History Summary

Generated On: 11 Aug 2021 22:42:38

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
User closed query 'Per source please add Environmental Allergies 2006 still ongoing to EDC Med History. ' (Site from CRA).	(b) (4), (b) (6)	22 Jan 2021 00:34:01
Query 'Per source please add Environmental Allergies 2006 still ongoing to EDC Med History. ' answered with 'updated' (Site from CRA).	Alexander Mills (b) (4)	14 Jan 2021 21:26:04
User opened query 'Per source please add Environmental Allergies 2006 still ongoing to EDC Med History. ' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 16:18:53
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 20:26:06

US3432580

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:42:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:23:18
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4)	23 Oct 2020 15:46:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Oct 2020 15:46:36
Data point term sent to Coder	System	23 Oct 2020 15:45:29
DataPoint Un-verified.	Monica Feeley (b) (4)	23 Oct 2020 15:45:18
Coding entries removed.	(b) (4)	
	Monica Feeley (b) (4)	23 Oct 2020 15:45:18
User entered 'ASTHMA (MILD)' reason for change:	(b) (4)	
Data Entry Error	Monica Feeley (b) (4)	23 Oct 2020 15:45:18
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 16:20:40
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4)	01 Oct 2020 20:28:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	01 Oct 2020 20:28:53
Data point term sent to Coder	System	01 Oct 2020 20:28:14
User entered 'Asthma'	(b) (4), (b) (6)	01 Oct 2020 20:27:14

US3432580

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:40
User entered 'un UNK 1980'	(b) (4), (b) (6)	01 Oct 2020 20:27:14

US3432580

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:42:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:40
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 20:27:14

US3432580

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:42:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 20:27:14

US3432580

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:40
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:27:14

US3432580

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:42:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:40
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 20:27:14

US3432580

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered 'Jan 1980'	System	01 Oct 2020 20:27:14

US3432580

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered '1980'	System	01 Oct 2020 20:27:14

US3432580

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered empty.	System	01 Oct 2020 20:27:14

US3432580

Folder: Screening

Form: Medical History (1)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered empty.	System	01 Oct 2020 20:27:14

US3432580

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:42:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:40
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 20:28:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 20:28:52
Data point term sent to Coder	System	01 Oct 2020 20:28:14
User entered 'HTN'	(b) (4), (b) (6)	01 Oct 2020 20:27:37

US3432580

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:40
User entered 'un UNK 1995'	(b) (4), (b) (6)	01 Oct 2020 20:27:37

US3432580

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:42:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:40
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 20:27:37

US3432580

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:42:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 20:27:37

US3432580

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:40
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:27:37

US3432580

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:42:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:40
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 20:27:37

US3432580

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered 'Jan 1995'	System	01 Oct 2020 20:27:37

US3432580

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered '1995'	System	01 Oct 2020 20:27:37

US3432580

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered empty.	System	01 Oct 2020 20:27:37

US3432580

Folder: Screening

Form: Medical History (2)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered empty.	System	01 Oct 2020 20:27:37

US3432580

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:42:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:40
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 20:28:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 20:28:52
Data point term sent to Coder	System	01 Oct 2020 20:28:15
User entered 'Depression'	(b) (4), (b) (6)	01 Oct 2020 20:28:00

US3432580

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:40
User entered 'un UNK 2018'	(b) (4), (b) (6)	01 Oct 2020 20:28:00

US3432580

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:42:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:40
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 20:28:00

US3432580

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:42:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 20:28:00

US3432580

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:40
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:28:00

US3432580

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:42:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:40
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 20:28:00

US3432580

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered 'Jan 2018'	System	01 Oct 2020 20:28:00

US3432580

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered '2018'	System	01 Oct 2020 20:28:00

US3432580

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered empty.	System	01 Oct 2020 20:28:00

US3432580

Folder: Screening

Form: Medical History (3)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered empty.	System	01 Oct 2020 20:28:00

US3432580

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:42:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:40
User coded data point as SOC: Psychiatric disorders, HLGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 20:30:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 20:30:51
Data point term sent to Coder	System	01 Oct 2020 20:29:18
User entered 'Insomnia'	(b) (4), (b) (6)	01 Oct 2020 20:28:34

US3432580

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:40
User entered 'un UNK 2018'	(b) (4), (b) (6)	01 Oct 2020 20:28:34

US3432580

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:42:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:40
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 20:28:34

US3432580

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:42:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 20:28:34

US3432580

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:40
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:28:34

US3432580

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:42:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:40
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 20:28:34

US3432580

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered 'Jan 2018'	System	01 Oct 2020 20:28:34

US3432580

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered '2018'	System	01 Oct 2020 20:28:34

US3432580

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered empty.	System	01 Oct 2020 20:28:34

US3432580

Folder: Screening

Form: Medical History (4)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered empty.	System	01 Oct 2020 20:28:34

US3432580

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:42:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:40
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 20:30:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Oct 2020 20:30:51
Data point term sent to Coder	System	01 Oct 2020 20:29:20
User entered 'GERD'	(b) (4), (b) (6)	01 Oct 2020 20:29:01

US3432580

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:40
User entered 'un UNK 2019'	(b) (4), (b) (6)	01 Oct 2020 20:29:01

US3432580

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:42:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:40
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 20:29:01

US3432580

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:42:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 20:29:01

US3432580

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:40
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:29:01

US3432580

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:42:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:40
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 20:29:01

US3432580

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered 'Jan 2019'	System	01 Oct 2020 20:29:01

US3432580

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered '2019'	System	01 Oct 2020 20:29:01

US3432580

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered empty.	System	01 Oct 2020 20:29:01

US3432580

Folder: Screening

Form: Medical History (5)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered empty.	System	01 Oct 2020 20:29:01

US3432580

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:42:38

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:23:42
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Eczema, LLT: Eczema - version MedDRA\\23.0.	Coder Import (b) (4)	22 Oct 2020 15:04:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Oct 2020 15:04:39
Data point term sent to Coder	System	22 Oct 2020 14:03:40
User entered 'eczema (right middle digit)'	(b) (4), (b) (6)	22 Oct 2020 14:02:58

US3432580

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:23:42
User entered 'un Mar 2020'	(b) (4), (b) (6)	22 Oct 2020 14:02:58

US3432580

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:42:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:23:42
User entered '0'	(b) (4), (b) (6)	22 Oct 2020 14:02:58

US3432580

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:42:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:23:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Oct 2020 14:02:58

US3432580

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:23:42
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 14:02:58

US3432580

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:42:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:23:42
User entered '0'	(b) (4), (b) (6)	22 Oct 2020 14:02:58

US3432580

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered 'Mar 2020'	System	22 Oct 2020 14:02:58

US3432580

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered '2020'	System	22 Oct 2020 14:02:58

US3432580

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered empty.	System	22 Oct 2020 14:02:58

US3432580

Folder: Screening

Form: Medical History (6)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered empty.	System	22 Oct 2020 14:02:58

US3432580

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:42:38

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 14:45:32
User coded data point as SOC: Immune system disorders, HLG: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Environmental allergy - version MedDRA\23.0.	Coder Import (b) (4)	14 Jan 2021 21:26:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	14 Jan 2021 21:26:57
Data point term sent to Coder	System	14 Jan 2021 21:26:17
User entered 'Environmental allergies'	Alexander Mills (b) (4)	14 Jan 2021 21:25:56

US3432580

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 14:45:34
User entered 'un UNK 2006'	Alexander Mills (b) (4)	14 Jan 2021 21:25:56

US3432580

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:42:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 14:45:35
User entered '0'	Alexander Mills (b) (4)	14 Jan 2021 21:25:56

US3432580

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:42:38

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 14:45:37
User entered 'Yes (Y)'	Alexander Mills (b) (4)	14 Jan 2021 21:25:56

US3432580

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 14:45:39
User entered empty.	Alexander Mills (b) (4)	14 Jan 2021 21:25:56

US3432580

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:42:38

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	20 Jan 2021 14:45:40
User entered '0'	Alexander Mills (b) (4)	14 Jan 2021 21:25:56

US3432580

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered 'Jan 2006'	System	14 Jan 2021 21:25:56

US3432580

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered '2006'	System	14 Jan 2021 21:25:56

US3432580

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered empty.	System	14 Jan 2021 21:25:56

US3432580

Folder: Screening

Form: Medical History (7)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered empty.	System	14 Jan 2021 21:25:56

US3432580

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:07:16
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 20:25:13

US3432580

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:07:16
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 20:25:13

US3432580

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:07:16
User entered '10:49'	(b) (4), (b) (6)	01 Oct 2020 20:25:13

US3432580

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered '1 Oct 2020 10:49'	System	01 Oct 2020 20:25:13

US3432580

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:07:16
User entered '158.5' cm	(b) (4), (b) (6)	01 Oct 2020 20:25:13
DataPoint set to visible.	System	01 Oct 2020 16:45:29

US3432580

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:07:16
User entered '74.6' kg	(b) (4), (b) (6)	01 Oct 2020 20:25:13
DataPoint set to visible.	System	01 Oct 2020 16:45:29

US3432580

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered '29.69479'	System	01 Oct 2020 20:25:13
DataPoint set to visible.	System	01 Oct 2020 16:45:29

US3432580

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered 'kg/m2'	System	01 Oct 2020 20:25:13
DataPoint set to visible.	System	01 Oct 2020 16:45:29

US3432580

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:07:16
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Oct 2020 20:25:13

US3432580

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:07:16
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:25:13

US3432580

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:07:16
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:25:13

US3432580

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:07:16
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Oct 2020 20:25:13

US3432580

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered 'bpm'	System	01 Oct 2020 20:25:13

US3432580

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:07:16
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Oct 2020 20:25:13

US3432580

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered 'breaths/min'	System	01 Oct 2020 20:25:13

US3432580

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:07:16
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Oct 2020 20:25:13

US3432580

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered 'mmHg'	System	01 Oct 2020 20:25:13

US3432580

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:07:16
User entered missing code ND - Not Done.	(b) (4), (b) (6)	01 Oct 2020 20:25:13

US3432580

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered 'mmHg'	System	01 Oct 2020 20:25:13

US3432580

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10

US3432580

Folder: Screening

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10

US3432580

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:42:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:07:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 20:25:50

US3432580

Folder: Screening

Form: Physical Examination

Generated On: 11 Aug 2021 22:42:38

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:07:26
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 20:25:50

US3432580

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:42:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:20:06
User entered '1 Oct 2020'	Monica Feeley (b) (4)	27 Oct 2020 19:52:23

US3432580

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:42:38

Is the participant of childbearing potential?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:20:06
User closed query 'Per CDM: Participant is recorded to be of childbearing potential but Pregnancy Test page under Screening Visit is not completed. Please update. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 07:54:57
Query 'Per CDM: Participant is recorded to be of childbearing potential but Pregnancy Test page under Screening Visit is not completed. Please update. ' answered with 'updated' (Site from DM).	Julia Klopfer (b) (4)	10 Nov 2020 20:24:50
User opened query 'Per CDM: Participant is recorded to be of childbearing potential but Pregnancy Test page under Screening Visit is not completed. Please update. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 14:00:37
User entered 'Yes (Y)'	Monica Feeley (b) (4)	27 Oct 2020 19:52:23

US3432580

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:42:38

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:20:06
User entered empty.	Monica Feeley (b) (4)	27 Oct 2020 19:52:23

US3432580

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:42:38

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:20:06
User entered empty.	Monica Feeley (b) (4)	27 Oct 2020 19:52:23

US3432580

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:20:06
User entered empty.	Monica Feeley (b) (4)	27 Oct 2020 19:52:23

US3432580

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:42:38

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:20:06
User entered '0'	Monica Feeley (b) (4)	27 Oct 2020 19:52:23

US3432580

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:20:06
User entered empty.	Monica Feeley (b) (4)	27 Oct 2020 19:52:23

US3432580

Folder: Screening

Form: Childbearing Potential

Generated On: 11 Aug 2021 22:42:38

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:20:06
User entered '0'	Monica Feeley (b) (4)	27 Oct 2020 19:52:23

US3432580

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:42:38

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:20:32
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	10 Nov 2020 20:24:34

US3432580

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:42:38

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:20:32
User entered '01 Oct 2020'	Julia Klopfer (b) (4)	10 Nov 2020 20:24:34

US3432580

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:42:38

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:20:32
User entered 'Urine (URINE)'	Julia Klopfer (b) (4)	10 Nov 2020 20:24:34

US3432580

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:42:38

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:20:32
User entered 'Negative (NEGATIVE)'	Julia Klopfer (b) (4)	10 Nov 2020 20:24:34

US3432580

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:42:38

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:20:32
User entered 'No (N)'	Julia Klopfer (b) (4)	10 Nov 2020 20:24:34

US3432580

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:42:38

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:20:32
User entered empty.	Julia Klopfer (b) (4)	10 Nov 2020 20:24:34

US3432580

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:42:38

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:20:32
User entered empty.	Julia Klopfer (b) (4)	10 Nov 2020 20:24:34

US3432580

Folder: Screening

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:42:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered empty.	System	10 Nov 2020 20:24:34

US3432580

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:42:38

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:59
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 20:31:36
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 20:31:24

US3432580

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:42:38

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:59
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 20:31:24

US3432580

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:42:38

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:59
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 20:31:24

US3432580

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:42:38

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:59
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 20:31:24

US3432580

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:42:38

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:59
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 20:31:24

US3432580

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:42:38

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:59
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 20:31:24

US3432580

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:42:38

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:59
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 20:31:24

US3432580

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:42:38

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:59
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 20:31:24

US3432580

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:42:38

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:59
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 20:31:24

US3432580

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:42:38

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:59
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 20:31:24

US3432580

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:42:38

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:59
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 20:31:24

US3432580

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:42:38

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:59
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 20:31:24

US3432580

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:42:38

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:59
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:31:24

US3432580

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:42:38

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 20:31:24

US3432580

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:42:38

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:59
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 20:31:24

US3432580

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:42:38

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:59
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 20:31:24

US3432580

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:42:38

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:59
User entered 'l'	(b) (4), (b) (6)	01 Oct 2020 20:31:24

US3432580

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:42:38

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:59
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 20:31:24

US3432580

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:42:38

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:59
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 20:31:24

US3432580

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:42:38

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 20:31:24

US3432580

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Aug 2021 22:42:38

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:20:59
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:31:24

US3432580

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:42:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
User closed query 'Per CDM: Participant is recorded to be of childbearing potential, however no data is recorded on Pregnancy test page for Visit 1. Please complete page per CCGs to avoid duplicate data. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 07:56:19
Query 'Per CDM: Participant is recorded to be of childbearing potential, however no data is recorded on Pregnancy test page for Visit 1. Please complete page per CCGs to avoid duplicate data. ' answered with 'Updated -- same as screening day' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 21:27:32
User opened query 'Per CDM: Participant is recorded to be of childbearing potential, however no data is recorded on Pregnancy test page for Visit 1. Please complete page per CCGs to avoid duplicate data. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 14:01:43
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:21:20
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	01 Oct 2020 16:45:39

US3432580

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:21:20
User entered '1 Oct 2020'	Phoebe Cunningham (b) (4)	01 Oct 2020 16:45:39

US3432580

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:42:38

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:21:20
User entered 'Clinic (Clinic)'	Phoebe Cunningham (b) (4)	01 Oct 2020 16:45:39

US3432580

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Aug 2021 22:42:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered 'VISIT1'	System	01 Oct 2020 16:45:39

US3432580

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:58:19
User entered '01 OCT 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Oct 2020 15:17:38

US3432580

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:42:38

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:58:16
User entered '116145'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Oct 2020 15:17:38

US3432580

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:42:38

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:58:15
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	01 Oct 2020 15:17:38

US3432580

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:42:38

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)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 14:25:29
User closed query 'Please add all fields.' (Site from CRA).	(b) (4), (b) (6)	26 Oct 2020 14:25:27
Query 'Please add all fields.' answered by data change (Site from CRA).	System	23 Oct 2020 15:44:43
User entered 'No (N)'	Monica Feeley (b) (4)	23 Oct 2020 15:44:43
User opened query 'Please add all fields.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 15:58:12

US3432580

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:42:38

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)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 14:25:29
User entered 'No (N)'	Monica Feeley (b) (4)	23 Oct 2020 15:44:43

US3432580

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:42:38

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 14:25:29
User entered 'No (N)'	Monica Feeley (b) (4)	23 Oct 2020 15:44:43

US3432580

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:42:38

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 14:25:29
User entered 'No (N)'	Monica Feeley (b) (4)	23 Oct 2020 15:44:43

US3432580

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:42:38

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 14:25:29
User entered 'No (N)'	Monica Feeley (b) (4)	23 Oct 2020 15:44:43

US3432580

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Aug 2021 22:42:38

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 14:25:29
User entered 'No (N)'	Monica Feeley (b) (4)	23 Oct 2020 15:44:43
DataPoint set to visible.	(b) (4) System	01 Oct 2020 16:45:26

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:42:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:19:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 20:25:30
User entered '158.5' cm	(b) (4), (b) (6)	01 Oct 2020 20:22:03

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:42:38

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:19:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 20:25:30
User entered '74.6' kg	(b) (4), (b) (6)	01 Oct 2020 20:22:03

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:42:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:19:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 20:25:30
User entered '158.5' cm	(b) (4), (b) (6)	01 Oct 2020 20:22:03

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:42:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:19:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 20:25:30
User entered '74.6' kg	(b) (4), (b) (6)	01 Oct 2020 20:22:03

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	01 Oct 2020 20:22:03

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:19:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 20:22:03

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:19:09
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 20:22:03

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:19:09
User entered '10:49'	(b) (4), (b) (6)	01 Oct 2020 20:22:03

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered '1 Oct 2020 10:49'	System	01 Oct 2020 20:22:03

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:19:09
User entered '97.5' F	(b) (4), (b) (6)	01 Oct 2020 20:22:03

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:41:52
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Un-verified.	(b) (4), (b) (6)	16 Dec 2020 18:44:57
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 18:44:57
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:19:09
User entered 'Oral (Oral)'	(b) (4), (b) (6)	01 Oct 2020 20:22:03

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:41:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Un-verified.	(b) (4), (b) (6)	16 Dec 2020 18:44:57
User entered 'INFRARED' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 18:44:57
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:19:09
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:22:03

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:19:09
User entered '88'	(b) (4), (b) (6)	01 Oct 2020 20:22:03

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered 'bpm'	System	01 Oct 2020 20:22:03

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:19:09
User entered '14'	(b) (4), (b) (6)	01 Oct 2020 20:22:03

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered 'breaths/min'	System	01 Oct 2020 20:22:03

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:19:09
User entered '121'	(b) (4), (b) (6)	01 Oct 2020 20:22:03

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered 'mmHg'	System	01 Oct 2020 20:22:03

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:19:09
User entered '75'	(b) (4), (b) (6)	01 Oct 2020 20:22:03

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered 'mmHg'	System	01 Oct 2020 20:22:03

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:42:38

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:19:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 20:25:30
User entered '158.5' cm	(b) (4), (b) (6)	01 Oct 2020 20:22:03

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Aug 2021 22:42:38

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:19:09
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	01 Oct 2020 20:25:30
User entered '74.6' kg	(b) (4), (b) (6)	01 Oct 2020 20:22:03

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	01 Oct 2020 20:22:03

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:19:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 20:22:03

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:19:09
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 20:22:03

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:19:09
User entered '12:54'	(b) (4), (b) (6)	01 Oct 2020 20:22:03

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered '1 Oct 2020 12:54'	System	01 Oct 2020 20:22:03

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:19:09
User entered '97.5' F	(b) (4), (b) (6)	01 Oct 2020 20:22:03

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:42:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Un-verified.	(b) (4), (b) (6)	16 Dec 2020 18:46:22
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 18:46:22
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:19:09
User entered 'Oral (Oral)'	(b) (4), (b) (6)	01 Oct 2020 20:22:03

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:42:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Un-verified.	(b) (4), (b) (6)	16 Dec 2020 18:46:22
User entered 'INFRARED' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Dec 2020 18:46:22
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:19:09
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:22:03

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:19:09
User entered '76'	(b) (4), (b) (6)	01 Oct 2020 20:22:03

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered 'bpm'	System	01 Oct 2020 20:22:03

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:19:09
User entered '14'	(b) (4), (b) (6)	01 Oct 2020 20:22:03

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered 'breaths/min'	System	01 Oct 2020 20:22:03

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:19:09
User entered '131'	(b) (4), (b) (6)	01 Oct 2020 20:22:03

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered 'mmHg'	System	01 Oct 2020 20:22:03

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:19:09
User entered '82'	(b) (4), (b) (6)	01 Oct 2020 20:22:03

US3432580

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered 'mmHg'	System	01 Oct 2020 20:22:03

US3432580

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:42:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:19:38
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 15:44:07
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:44:05
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 20:23:50

US3432580

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Aug 2021 22:42:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:19:38
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 15:44:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:44:05
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:23:50

US3432580

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:42:38

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
DataPoint Verified.	(b) (4), (b) (6)	27 Mar 2021 03:45:51
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 21:28:25
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 21:26:52

US3432580

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:42:38

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
DataPoint Verified.	(b) (4), (b) (6)	27 Mar 2021 03:45:51
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
User closed query 'Date of Test is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	12 Nov 2020 21:28:25
Query 'Date of Test is not equal to Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	12 Nov 2020 21:28:25
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 21:28:25
User opened query 'Date of Test is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	12 Nov 2020 21:26:52
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 21:26:52

US3432580

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:42:38

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
DataPoint Verified.	(b) (4), (b) (6)	27 Mar 2021 03:45:51
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 21:28:25
User entered 'Urine (URINE)'	(b) (4), (b) (6)	12 Nov 2020 21:26:52

US3432580

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:42:38

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
DataPoint Verified.	(b) (4), (b) (6)	27 Mar 2021 03:45:51
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 21:28:25
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	12 Nov 2020 21:26:52

US3432580

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:42:38

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
DataPoint Verified.	(b) (4), (b) (6)	27 Mar 2021 03:45:51
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
User closed query 'Per CDM: A response is required for this field. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 19:27:02
Query 'Per CDM: A response is required for this field. Please update accordingly.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 14:17:32
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 14:17:25
User opened query 'Per CDM: A response is required for this field. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 07:55:39
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	12 Nov 2020 21:28:25
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 21:26:52

US3432580

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:42:38

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
DataPoint Verified.	(b) (4), (b) (6)	27 Mar 2021 03:45:51
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 21:26:52

US3432580

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:42:38

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
DataPoint Verified.	(b) (4), (b) (6)	27 Mar 2021 03:45:51
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 21:26:52

US3432580

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:42:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered empty.	System	12 Nov 2020 21:26:52

US3432580

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:42:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:22:15
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	01 Oct 2020 16:45:52

US3432580

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:42:38

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:22:15
User entered empty.	Phoebe Cunningham (b) (4)	01 Oct 2020 16:45:52

US3432580

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:22:15
User entered empty.	Phoebe Cunningham (b) (4)	01 Oct 2020 16:45:52

US3432580

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:42:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered 'MRNA-1273 OR PLACEBO'	System	01 Oct 2020 16:45:52

US3432580

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:42:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:22:15
User entered '1 Oct 2020'	Phoebe Cunningham (b) (4)	01 Oct 2020 16:45:52

US3432580

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:42:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:22:15
User entered '12:23'	Phoebe Cunningham (b) (4)	01 Oct 2020 16:45:52

US3432580

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:42:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered '1 Oct 2020 12:23'	System	01 Oct 2020 16:45:52

US3432580

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:42:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:22:15
User entered 'Left Arm (LEFT ARM)'	Phoebe Cunningham (b) (4)	01 Oct 2020 16:45:52

US3432580

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:42:38

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:22:15
User entered 'ONCE'	System	01 Oct 2020 16:45:52

US3432580

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Aug 2021 22:42:38

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered 'INTRAMUSCULAR'	System	01 Oct 2020 16:45:52

US3432580

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:42:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:23:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 20:22:40

US3432580

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:42:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:23:11
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 20:22:40

US3432580

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:42:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:23:11
User entered '11:20'	(b) (4), (b) (6)	01 Oct 2020 20:22:40

US3432580

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:42:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered '1 Oct 2020 11:20'	System	01 Oct 2020 20:22:40

US3432580

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:42:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:23:20
User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	03 Oct 2020 11:46:16
Query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' answered by data change (Site from System).	System	03 Oct 2020 11:46:16
User entered '1 Oct 2020' reason for change: Data Entry Error	Monica Feeley (b) (4)	03 Oct 2020 11:46:16
User opened query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	01 Oct 2020 20:22:52
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:22:52

US3432580

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:42:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	01 Oct 2020 20:22:52

US3432580

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:42:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:23:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 20:22:52

US3432580

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:42:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:23:20
User entered '11:35'	(b) (4), (b) (6)	01 Oct 2020 20:22:52

US3432580

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:42:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered '1 Oct 2020 11:35'	System	03 Oct 2020 11:46:16
User entered empty.	System	01 Oct 2020 20:22:52

US3432580

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:42:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	01 Oct 2020 20:22:52

US3432580

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:42:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:23:20
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 20:22:52

US3432580

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:42:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:23:20
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:22:52

US3432580

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:42:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered empty.	System	01 Oct 2020 20:22:52

US3432580

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:42:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:05:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 20:33:00

US3432580

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Aug 2021 22:42:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered 'I'	System	01 Oct 2020 20:33:00

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	01 Oct 2020 16:45:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-01T12:55:17', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '2e82e9b8-ac6a-417b-89e7-ffbdb1476bfd' User entered 'Yes (Y)'	System	01 Oct 2020 16:55:39
	System	01 Oct 2020 16:55:39

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-01T12:55:21', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '2e82e9b8-ac6a-417b-89e7-ffbdb1476bfd' User entered '97.5'	System	01 Oct 2020 16:55:39
	System	01 Oct 2020 16:55:39

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-01T12:55:29', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '2e82e9b8-ac6a-417b-89e7-ffbdb1476bfd' User entered 'No (N)'	System	01 Oct 2020 16:55:39
	System	01 Oct 2020 16:55:39

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-01T12:55:35', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '2e82e9b8-ac6a-417b-89e7-ffbdb1476bfd' User entered '01 Oct 2020 12:55'	System	01 Oct 2020 16:55:39
	System	01 Oct 2020 16:55:39

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '01 Oct 2020 12:43'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '01 Oct 2020 15:13'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	01 Oct 2020 16:45:52
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-02T03:53:16', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '63ff970a-4007-4691-a906-e208b6f69778' User entered 'Yes (Y)'	System	02 Oct 2020 07:53:40
	System	02 Oct 2020 07:53:40

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-02T03:53:21', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '63ff970a-4007-4691-a906-e208b6f69778' User entered '97.7'	System	02 Oct 2020 07:53:40
	System	02 Oct 2020 07:53:40

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-02T03:53:23', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '63ff970a-4007-4691-a906-e208b6f69778'	System	02 Oct 2020 07:53:40
User entered 'No (N)'	System	02 Oct 2020 07:53:40

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-02T03:53:37', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '63ff970a-4007-4691-a906-e208b6f69778' User entered '02 Oct 2020 03:53'	System	02 Oct 2020 07:53:40
	System	02 Oct 2020 07:53:40

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '01 Oct 2020 16:08'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	01 Oct 2020 16:45:52
User entered 'Day 2'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:42:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-02T12:35:18', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '8822e56a-046b-4261-b3f6-9f05a687b060' User entered 'Yes (Y)'	System	02 Oct 2020 16:35:33
	System	02 Oct 2020 16:35:33

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:42:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-02T12:35:22', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '8822e56a-046b-4261-b3f6-9f05a687b060' User entered '97.6'	System	02 Oct 2020 16:35:33
	System	02 Oct 2020 16:35:33

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-02T12:35:27', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '8822e56a-046b-4261-b3f6-9f05a687b060' User entered 'No (N)'	System	02 Oct 2020 16:35:33
	System	02 Oct 2020 16:35:33

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:42:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-02T12:35:30', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '8822e56a-046b-4261-b3f6-9f05a687b060' User entered '02 Oct 2020 12:35'	System	02 Oct 2020 16:35:33
	System	02 Oct 2020 16:35:33

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	01 Oct 2020 16:45:52
User entered 'Day 3'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:42:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-03T14:29:32', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '4f186c9f-bc1b-4b8f-b05d-d3b34959945e' User entered 'Yes (Y)'	System	03 Oct 2020 18:29:45
	System	03 Oct 2020 18:29:45

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:42:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-03T14:29:36', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '4f186c9f-bc1b-4b8f-b05d-d3b34959945e' User entered '98.5'	System	03 Oct 2020 18:29:45
	System	03 Oct 2020 18:29:45

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-03T14:29:38', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '4f186c9f-bc1b-4b8f-b05d-d3b34959945e' User entered 'No (N)'	System	03 Oct 2020 18:29:45
	System	03 Oct 2020 18:29:45

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:42:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-03T14:29:41', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '4f186c9f-bc1b-4b8f-b05d-d3b34959945e' User entered '03 Oct 2020 14:29'	System	03 Oct 2020 18:29:45
	System	03 Oct 2020 18:29:45

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	01 Oct 2020 16:45:52
User entered 'Day 4'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:42:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-04T23:31:44', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '56709dc7-0095-4ef3-9646-0bc2a7d3a6f0' User entered 'Yes (Y)'	System	05 Oct 2020 03:31:57
	System	05 Oct 2020 03:31:57

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:42:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-04T23:31:49', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '56709dc7-0095-4ef3-9646-0bc2a7d3a6f0' User entered '97.3'	System	05 Oct 2020 03:31:57
	System	05 Oct 2020 03:31:57

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-04T23:31:52', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '56709dc7-0095-4ef3-9646-0bc2a7d3a6f0' User entered 'No (N)'	System	05 Oct 2020 03:31:57
	System	05 Oct 2020 03:31:57

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:42:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-04T23:31:54', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '56709dc7-0095-4ef3-9646-0bc2a7d3a6f0' User entered '04 Oct 2020 23:31'	System	05 Oct 2020 03:31:57
	System	05 Oct 2020 03:31:57

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	01 Oct 2020 16:45:52
User entered 'Day 5'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:42:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-05T17:48:42', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '661967c5-6a45-49c3-aa46-f5d6304b2317' User entered 'Yes (Y)'	System	05 Oct 2020 21:48:53
	System	05 Oct 2020 21:48:53

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:42:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-05T17:48:46', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '661967c5-6a45-49c3-aa46-f5d6304b2317' User entered '97.6'	System	05 Oct 2020 21:48:53
	System	05 Oct 2020 21:48:53

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-05T17:48:48', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '661967c5-6a45-49c3-aa46-f5d6304b2317' User entered 'No (N)'	System	05 Oct 2020 21:48:53
	System	05 Oct 2020 21:48:53

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:42:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-05T17:48:51', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '661967c5-6a45-49c3-aa46-f5d6304b2317' User entered '05 Oct 2020 17:48'	System	05 Oct 2020 21:48:53
	System	05 Oct 2020 21:48:53

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	01 Oct 2020 16:45:52
User entered 'Day 6'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:42:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-06T19:52:25', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'fb812646-2dbf-4a26-b809-331e24598f8f' User entered 'Yes (Y)'	System	06 Oct 2020 23:52:37
	System	06 Oct 2020 23:52:37

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:42:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-06T19:52:28', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'fb812646-2dbf-4a26-b809-331e24598f8f' User entered '98.2'	System	06 Oct 2020 23:52:37
	System	06 Oct 2020 23:52:37

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-06T19:52:30', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'fb812646-2dbf-4a26-b809-331e24598f8f' User entered 'No (N)'	System	06 Oct 2020 23:52:37
	System	06 Oct 2020 23:52:37

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:42:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-06T19:52:32', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'fb812646-2dbf-4a26-b809-331e24598f8f' User entered '06 Oct 2020 19:52'	System	06 Oct 2020 23:52:37
	System	06 Oct 2020 23:52:37

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	01 Oct 2020 16:45:52
User entered 'Day 7'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:42:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-07T22:14:32', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'a98d3dc9-8ffb-4dd0-be66-a15810342e36' User entered 'Yes (Y)'	System	08 Oct 2020 02:15:11
	System	08 Oct 2020 02:15:11

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:42:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-07T22:15:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'a98d3dc9-8ffb-4dd0-be66-a15810342e36' User entered '97.5'	System	08 Oct 2020 02:15:11
	System	08 Oct 2020 02:15:11

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-07T22:15:04', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'a98d3dc9-8ffb-4dd0-be66-a15810342e36'	System	08 Oct 2020 02:15:11
User entered 'No (N)'	System	08 Oct 2020 02:15:11

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:42:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-07T22:15:07', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'a98d3dc9-8ffb-4dd0-be66-a15810342e36' User entered '07 Oct 2020 22:15'	System	08 Oct 2020 02:15:11
	System	08 Oct 2020 02:15:11

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	01 Oct 2020 16:45:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-01T12:55:46', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '885e35b0-7264-438b-aa65-1797578f149a' User entered 'None (1)'	System	01 Oct 2020 16:56:08
	System	01 Oct 2020 16:56:08

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-01T12:55:50', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '885e35b0-7264-438b-aa65-1797578f149a' User entered 'No (N)'	System	01 Oct 2020 16:56:08
	System	01 Oct 2020 16:56:08

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-01T12:55:54', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '885e35b0-7264-438b-aa65-1797578f149a' User entered 'No (N)'	System	01 Oct 2020 16:56:08
	System	01 Oct 2020 16:56:08

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-01T12:56:01', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '885e35b0-7264-438b-aa65-1797578f149a'	System	01 Oct 2020 16:56:08
User entered 'None (1)'	System	01 Oct 2020 16:56:08

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-01T12:56:04', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '885e35b0-7264-438b-aa65-1797578f149a' User entered '01 Oct 2020 12:56'	System	01 Oct 2020 16:56:08
	System	01 Oct 2020 16:56:08

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '01 Oct 2020 12:43'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '01 Oct 2020 15:13'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	01 Oct 2020 16:45:52
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-02T03:53:45', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '2ebc84e6-24d2-4d92-8326-e81d088a3117'	System	02 Oct 2020 07:54:22
User entered 'Does not interfere with activity (2)'	System	02 Oct 2020 07:54:22

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-02T03:53:49', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '2ebc84e6-24d2-4d92-8326-e81d088a3117'	System	02 Oct 2020 07:54:22
User entered 'No (N)'	System	02 Oct 2020 07:54:22

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-02T03:54:06', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '2ebc84e6-24d2-4d92-8326-e81d088a3117' User entered 'No (N)'	System	02 Oct 2020 07:54:22
	System	02 Oct 2020 07:54:22

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-02T03:54:13', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '2ebc84e6-24d2-4d92-8326-e81d088a3117'	System	02 Oct 2020 07:54:22
User entered 'None (1)'	System	02 Oct 2020 07:54:22

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-02T03:54:20', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '2ebc84e6-24d2-4d92-8326-e81d088a3117' User entered '02 Oct 2020 03:54'	System	02 Oct 2020 07:54:22
	System	02 Oct 2020 07:54:22

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '01 Oct 2020 16:08'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	01 Oct 2020 16:45:52
User entered 'Day 2'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:42:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-02T12:35:45', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'd3df20a2-ac4d-45e9-8072-48e0511c8eae'	System	02 Oct 2020 16:36:57
User entered 'Does not interfere with activity (2)'	System	02 Oct 2020 16:36:57

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:42:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-02T12:36:32', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'd3df20a2-ac4d-45e9-8072-48e0511c8eae' User entered 'No (N)'	System	02 Oct 2020 16:36:57
	System	02 Oct 2020 16:36:57

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-02T12:36:45', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'd3df20a2-ac4d-45e9-8072-48e0511c8eae' User entered 'No (N)'	System	02 Oct 2020 16:36:57
	System	02 Oct 2020 16:36:57

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:42:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-02T12:36:50', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'd3df20a2-ac4d-45e9-8072-48e0511c8eae' User entered 'None (1)'	System	02 Oct 2020 16:36:57
	System	02 Oct 2020 16:36:57

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:42:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-02T12:36:53', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'd3df20a2-ac4d-45e9-8072-48e0511c8eae' User entered '02 Oct 2020 12:36'	System	02 Oct 2020 16:36:57
	System	02 Oct 2020 16:36:57

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	01 Oct 2020 16:45:52
User entered 'Day 3'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:42:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-03T14:27:49', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '845cdcc4-530e-4042-8fef-a80a372bbe94'	System	03 Oct 2020 18:28:01
User entered 'Does not interfere with activity (2)'	System	03 Oct 2020 18:28:01

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:42:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-03T14:27:51', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '845cdcc4-530e-4042-8fef-a80a372bbe94' User entered 'No (N)'	System	03 Oct 2020 18:28:01
	System	03 Oct 2020 18:28:01

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-03T14:27:53', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '845cdcc4-530e-4042-8fef-a80a372bbe94' User entered 'No (N)'	System	03 Oct 2020 18:28:01
	System	03 Oct 2020 18:28:01

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:42:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-03T14:27:56', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '845cdcc4-530e-4042-8fef-a80a372bbe94'	System	03 Oct 2020 18:28:01
User entered 'None (1)'	System	03 Oct 2020 18:28:01

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:42:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-03T14:27:58', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '845cdcc4-530e-4042-8fef-a80a372bbe94' User entered '03 Oct 2020 14:27'	System	03 Oct 2020 18:28:01
	System	03 Oct 2020 18:28:01

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	01 Oct 2020 16:45:52
User entered 'Day 4'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:42:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-04T23:31:08', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '39ff736f-fb32-46fd-b4d4-29004a1715d9'	System	05 Oct 2020 03:31:20
User entered 'Does not interfere with activity (2)'	System	05 Oct 2020 03:31:20

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:42:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-04T23:31:10', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '39ff736f-fb32-46fd-b4d4-29004a1715d9' User entered 'No (N)'	System	05 Oct 2020 03:31:20
	System	05 Oct 2020 03:31:20

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-04T23:31:12', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '39ff736f-fb32-46fd-b4d4-29004a1715d9' User entered 'No (N)'	System	05 Oct 2020 03:31:20
	System	05 Oct 2020 03:31:20

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:42:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-04T23:31:15', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '39ff736f-fb32-46fd-b4d4-29004a1715d9'	System	05 Oct 2020 03:31:20
User entered 'None (1)'	System	05 Oct 2020 03:31:20

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:42:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-04T23:31:18', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '39ff736f-fb32-46fd-b4d4-29004a1715d9' User entered '04 Oct 2020 23:31'	System	05 Oct 2020 03:31:20
	System	05 Oct 2020 03:31:20

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	01 Oct 2020 16:45:52
User entered 'Day 5'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:42:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-05T17:48:08', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '6476f8b5-244e-439a-84ea-1da0bd4e1a89'	System	05 Oct 2020 21:48:20
User entered 'None (1)'	System	05 Oct 2020 21:48:20

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:42:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-05T17:48:10', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '6476f8b5-244e-439a-84ea-1da0bd4e1a89' User entered 'No (N)'	System	05 Oct 2020 21:48:20
	System	05 Oct 2020 21:48:20

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-05T17:48:12', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '6476f8b5-244e-439a-84ea-1da0bd4e1a89' User entered 'No (N)'	System	05 Oct 2020 21:48:20
	System	05 Oct 2020 21:48:20

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:42:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-05T17:48:13', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '6476f8b5-244e-439a-84ea-1da0bd4e1a89'	System	05 Oct 2020 21:48:20
User entered 'None (1)'	System	05 Oct 2020 21:48:20

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:42:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-05T17:48:17', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '6476f8b5-244e-439a-84ea-1da0bd4e1a89' User entered '05 Oct 2020 17:48'	System	05 Oct 2020 21:48:20
	System	05 Oct 2020 21:48:20

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	01 Oct 2020 16:45:52
User entered 'Day 6'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:42:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-06T19:52:43', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '95ab0d5e-9e91-4215-9689-f08106a8a296'	System	06 Oct 2020 23:53:04
User entered 'None (1)'	System	06 Oct 2020 23:53:04

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:42:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-06T19:52:49', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '95ab0d5e-9e91-4215-9689-f08106a8a296' User entered 'No (N)'	System	06 Oct 2020 23:53:04
	System	06 Oct 2020 23:53:04

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-06T19:52:50', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '95ab0d5e-9e91-4215-9689-f08106a8a296' User entered 'No (N)'	System	06 Oct 2020 23:53:04
	System	06 Oct 2020 23:53:04

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:42:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-06T19:52:52', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '95ab0d5e-9e91-4215-9689-f08106a8a296'	System	06 Oct 2020 23:53:04
User entered 'None (1)'	System	06 Oct 2020 23:53:04

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:42:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-06T19:52:59', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '95ab0d5e-9e91-4215-9689-f08106a8a296' User entered '06 Oct 2020 19:52'	System	06 Oct 2020 23:53:04
	System	06 Oct 2020 23:53:04

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	01 Oct 2020 16:45:52
User entered 'Day 7'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:42:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-07T22:14:06', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'ff76a286-bfac-4976-bf27-d68190a1f35e'	System	08 Oct 2020 02:14:17
User entered 'None (1)'	System	08 Oct 2020 02:14:17

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:42:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-07T22:14:07', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'ff76a286-bfac-4976-bf27-d68190a1f35e' User entered 'No (N)'	System	08 Oct 2020 02:14:17
	System	08 Oct 2020 02:14:17

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-07T22:14:09', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'ff76a286-bfac-4976-bf27-d68190a1f35e' User entered 'No (N)'	System	08 Oct 2020 02:14:17
	System	08 Oct 2020 02:14:17

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:42:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-07T22:14:10', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'ff76a286-bfac-4976-bf27-d68190a1f35e' User entered 'None (1)'	System	08 Oct 2020 02:14:17
	System	08 Oct 2020 02:14:17

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:42:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-07T22:14:13', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'ff76a286-bfac-4976-bf27-d68190a1f35e' User entered '07 Oct 2020 22:14'	System	08 Oct 2020 02:14:17
	System	08 Oct 2020 02:14:17

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	01 Oct 2020 16:45:52
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-01T12:56:14', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'cddbb4c3-120f-41b1-b1f1-592b30ccf638'	System	01 Oct 2020 16:56:41
User entered 'No interference with activity (1)'	System	01 Oct 2020 16:56:41

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-01T12:56:24', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'cddbb4c3-120f-41b1-b1f1-592b30ccf638'	System	01 Oct 2020 16:56:41
User entered 'No interference with activity (1)'	System	01 Oct 2020 16:56:41

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-01T12:56:26', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'cddb4c3-120f-41b1-b1f1-592b30ccf638' User entered 'None (0)'	System	01 Oct 2020 16:56:41
	System	01 Oct 2020 16:56:41

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-01T12:56:29', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'cddbb4c3-120f-41b1-b1f1-592b30ccf638' User entered 'None (0)'	System	01 Oct 2020 16:56:41
	System	01 Oct 2020 16:56:41

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-01T12:56:30', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'cddb4c3-120f-41b1-b1f1-592b30ccf638' User entered 'None (0)'	System	01 Oct 2020 16:56:41
	System	01 Oct 2020 16:56:41

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-01T12:56:34', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'cddb4c3-120f-41b1-b1f1-592b30ccf638' User entered 'None (0)'	System	01 Oct 2020 16:56:41
	System	01 Oct 2020 16:56:41

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-01T12:56:37', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'cddb4c3-120f-41b1-b1f1-592b30ccf638' User entered 'No (N)'	System	01 Oct 2020 16:56:41
	System	01 Oct 2020 16:56:41

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-01T12:56:39', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'cddbb4c3-120f-41b1-b1f1-592b30ccf638' User entered '01 Oct 2020 12:56'	System	01 Oct 2020 16:56:41
	System	01 Oct 2020 16:56:41

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '01 Oct 2020 12:43'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '01 Oct 2020 15:13'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	01 Oct 2020 16:45:52
User entered 'Day 1, after vaccination (at home)'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-02T03:54:29', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '31d76442-6a9b-4f22-908f-d512c9e6e89b' User entered 'None (0)'	System	02 Oct 2020 07:54:58
	System	02 Oct 2020 07:54:58

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-02T03:54:36', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '31d76442-6a9b-4f22-908f-d512c9e6e89b' User entered 'No interference with activity (1)'	System	02 Oct 2020 07:54:58
	System	02 Oct 2020 07:54:58

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-02T03:54:41', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '31d76442-6a9b-4f22-908f-d512c9e6e89b' User entered 'None (0)'	System	02 Oct 2020 07:54:58
	System	02 Oct 2020 07:54:58

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-02T03:54:46', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '31d76442-6a9b-4f22-908f-d512c9e6e89b' User entered 'None (0)'	System	02 Oct 2020 07:54:58
	System	02 Oct 2020 07:54:58

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-02T03:54:49', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '31d76442-6a9b-4f22-908f-d512c9e6e89b' User entered 'None (0)'	System	02 Oct 2020 07:54:58
	System	02 Oct 2020 07:54:58

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-02T03:54:51', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '31d76442-6a9b-4f22-908f-d512c9e6e89b' User entered 'None (0)'	System	02 Oct 2020 07:54:58
	System	02 Oct 2020 07:54:58

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-02T03:54:53', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '31d76442-6a9b-4f22-908f-d512c9e6e89b' User entered 'No (N)'	System	02 Oct 2020 07:54:58
	System	02 Oct 2020 07:54:58

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-02T03:54:55', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '31d76442-6a9b-4f22-908f-d512c9e6e89b' User entered '02 Oct 2020 03:54'	System	02 Oct 2020 07:54:58
	System	02 Oct 2020 07:54:58

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '01 Oct 2020 16:08'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '02 Oct 2020 11:59'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	01 Oct 2020 16:45:52
User entered 'Day 2'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:42:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-02T12:36:56', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '21d998be-8c97-4343-b290-83dcd0feb77b' User entered 'None (0)'	System	02 Oct 2020 16:37:15
	System	02 Oct 2020 16:37:15

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:42:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-02T12:37:01', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '21d998be-8c97-4343-b290-83dcd0feb77b' User entered 'None (0)'	System	02 Oct 2020 16:37:15
	System	02 Oct 2020 16:37:15

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:42:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-02T12:37:05', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '21d998be-8c97-4343-b290-83dcd0feb77b' User entered 'None (0)'	System	02 Oct 2020 16:37:15
	System	02 Oct 2020 16:37:15

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:42:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-02T12:37:06', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '21d998be-8c97-4343-b290-83dcd0feb77b' User entered 'None (0)'	System	02 Oct 2020 16:37:15
	System	02 Oct 2020 16:37:15

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:42:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-02T12:37:07', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '21d998be-8c97-4343-b290-83dcd0feb77b' User entered 'None (0)'	System	02 Oct 2020 16:37:15
	System	02 Oct 2020 16:37:15

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:42:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-02T12:37:09', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '21d998be-8c97-4343-b290-83dcd0feb77b' User entered 'None (0)'	System	02 Oct 2020 16:37:15
	System	02 Oct 2020 16:37:15

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-02T12:37:11', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '21d998be-8c97-4343-b290-83dcd0feb77b' User entered 'No (N)'	System	02 Oct 2020 16:37:15
	System	02 Oct 2020 16:37:15

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:42:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-02T12:37:13', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '21d998be-8c97-4343-b290-83dcd0feb77b' User entered '02 Oct 2020 12:37'	System	02 Oct 2020 16:37:15
	System	02 Oct 2020 16:37:15

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '02 Oct 2020 12:00'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '03 Oct 2020 11:59'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	01 Oct 2020 16:45:52
User entered 'Day 3'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:42:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-03T14:28:03', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '11a26b1d-0bbe-4eac-90b1-b23a6faa9f21' User entered 'None (0)'	System	03 Oct 2020 18:28:18
	System	03 Oct 2020 18:28:18

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:42:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-03T14:28:05', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '11a26b1d-0bbe-4eac-90b1-b23a6faa9f21' User entered 'None (0)'	System	03 Oct 2020 18:28:18
	System	03 Oct 2020 18:28:18

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:42:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-03T14:28:07', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '11a26b1d-0bbe-4eac-90b1-b23a6faa9f21' User entered 'None (0)'	System	03 Oct 2020 18:28:18
	System	03 Oct 2020 18:28:18

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:42:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-03T14:28:09', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '11a26b1d-0bbe-4eac-90b1-b23a6faa9f21' User entered 'None (0)'	System	03 Oct 2020 18:28:18
	System	03 Oct 2020 18:28:18

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:42:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-03T14:28:10', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '11a26b1d-0bbe-4eac-90b1-b23a6faa9f21' User entered 'None (0)'	System	03 Oct 2020 18:28:18
	System	03 Oct 2020 18:28:18

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:42:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-03T14:28:12', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '11a26b1d-0bbe-4eac-90b1-b23a6faa9f21' User entered 'None (0)'	System	03 Oct 2020 18:28:18
	System	03 Oct 2020 18:28:18

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-03T14:28:14', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '11a26b1d-0bbe-4eac-90b1-b23a6faa9f21' User entered 'No (N)'	System	03 Oct 2020 18:28:18
	System	03 Oct 2020 18:28:18

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:42:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-03T14:28:17', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '11a26b1d-0bbe-4eac-90b1-b23a6faa9f21' User entered '03 Oct 2020 14:28'	System	03 Oct 2020 18:28:18
	System	03 Oct 2020 18:28:18

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	01 Oct 2020 16:45:52
User entered 'Day 4'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:42:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-04T23:31:24', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '1e395c4c-a7a5-4770-bed2-cb0401c03673' User entered 'None (0)'	System	05 Oct 2020 03:31:41
	System	05 Oct 2020 03:31:41

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:42:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-04T23:31:28', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '1e395c4c-a7a5-4770-bed2-cb0401c03673' User entered 'None (0)'	System	05 Oct 2020 03:31:41
	System	05 Oct 2020 03:31:41

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:42:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-04T23:31:29', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '1e395c4c-a7a5-4770-bed2-cb0401c03673' User entered 'None (0)'	System	05 Oct 2020 03:31:41
	System	05 Oct 2020 03:31:41

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:42:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-04T23:31:31', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '1e395c4c-a7a5-4770-bed2-cb0401c03673' User entered 'None (0)'	System	05 Oct 2020 03:31:41
	System	05 Oct 2020 03:31:41

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:42:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-04T23:31:32', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '1e395c4c-a7a5-4770-bed2-cb0401c03673' User entered 'None (0)'	System	05 Oct 2020 03:31:41
	System	05 Oct 2020 03:31:41

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:42:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-04T23:31:33', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '1e395c4c-a7a5-4770-bed2-cb0401c03673' User entered 'None (0)'	System	05 Oct 2020 03:31:41
	System	05 Oct 2020 03:31:41

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-04T23:31:35', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '1e395c4c-a7a5-4770-bed2-cb0401c03673' User entered 'No (N)'	System	05 Oct 2020 03:31:41
	System	05 Oct 2020 03:31:41

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:42:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-04T23:31:37', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '1e395c4c-a7a5-4770-bed2-cb0401c03673' User entered '04 Oct 2020 23:31'	System	05 Oct 2020 03:31:41
	System	05 Oct 2020 03:31:41

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '04 Oct 2020 12:00'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '05 Oct 2020 11:59'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	01 Oct 2020 16:45:52
User entered 'Day 5'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:42:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-05T17:48:22', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '3ae7d72f-8b58-4085-81d4-ab1f838364ff' User entered 'None (0)'	System	05 Oct 2020 21:48:41
	System	05 Oct 2020 21:48:41

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:42:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-05T17:48:25', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '3ae7d72f-8b58-4085-81d4-ab1f838364ff' User entered 'None (0)'	System	05 Oct 2020 21:48:41
	System	05 Oct 2020 21:48:41

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:42:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-05T17:48:26', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '3ae7d72f-8b58-4085-81d4-ab1f838364ff' User entered 'None (0)'	System	05 Oct 2020 21:48:41
	System	05 Oct 2020 21:48:41

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:42:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-05T17:48:29', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '3ae7d72f-8b58-4085-81d4-ab1f838364ff' User entered 'None (0)'	System	05 Oct 2020 21:48:41
	System	05 Oct 2020 21:48:41

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:42:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-05T17:48:31', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '3ae7d72f-8b58-4085-81d4-ab1f838364ff' User entered 'None (0)'	System	05 Oct 2020 21:48:41
	System	05 Oct 2020 21:48:41

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:42:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-05T17:48:32', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '3ae7d72f-8b58-4085-81d4-ab1f838364ff' User entered 'None (0)'	System	05 Oct 2020 21:48:41
	System	05 Oct 2020 21:48:41

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-05T17:48:36', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '3ae7d72f-8b58-4085-81d4-ab1f838364ff' User entered 'No (N)'	System	05 Oct 2020 21:48:41
	System	05 Oct 2020 21:48:41

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:42:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-05T17:48:38', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '3ae7d72f-8b58-4085-81d4-ab1f838364ff' User entered '05 Oct 2020 17:48'	System	05 Oct 2020 21:48:41
	System	05 Oct 2020 21:48:41

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '05 Oct 2020 12:00'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '06 Oct 2020 11:59'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	01 Oct 2020 16:45:52
User entered 'Day 6'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:42:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-06T19:53:06', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '02b281f8-a5ff-404e-b95a-4b7ef727d3ec' User entered 'No interference with activity (1)'	System	06 Oct 2020 23:53:24
	System	06 Oct 2020 23:53:24

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:42:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-06T19:53:10', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '02b281f8-a5ff-404e-b95a-4b7ef727d3ec' User entered 'None (0)'	System	06 Oct 2020 23:53:24
	System	06 Oct 2020 23:53:24

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:42:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-06T19:53:11', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '02b281f8-a5ff-404e-b95a-4b7ef727d3ec' User entered 'None (0)'	System	06 Oct 2020 23:53:24
	System	06 Oct 2020 23:53:24

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:42:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-06T19:53:12', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '02b281f8-a5ff-404e-b95a-4b7ef727d3ec' User entered 'None (0)'	System	06 Oct 2020 23:53:24
	System	06 Oct 2020 23:53:24

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:42:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-06T19:53:13', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '02b281f8-a5ff-404e-b95a-4b7ef727d3ec' User entered 'None (0)'	System	06 Oct 2020 23:53:24
	System	06 Oct 2020 23:53:24

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:42:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-06T19:53:14', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '02b281f8-a5ff-404e-b95a-4b7ef727d3ec' User entered 'None (0)'	System	06 Oct 2020 23:53:24
	System	06 Oct 2020 23:53:24

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-06T19:53:20', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '02b281f8-a5ff-404e-b95a-4b7ef727d3ec' User entered 'No (N)'	System	06 Oct 2020 23:53:24
	System	06 Oct 2020 23:53:24

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:42:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-06T19:53:22', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '02b281f8-a5ff-404e-b95a-4b7ef727d3ec' User entered '06 Oct 2020 19:53'	System	06 Oct 2020 23:53:24
	System	06 Oct 2020 23:53:24

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '06 Oct 2020 12:00'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '07 Oct 2020 11:59'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	01 Oct 2020 16:45:52
User entered 'Day 7'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:42:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-07T22:14:15', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '295b685c-49a4-41d1-b7f1-5ec312502100' User entered 'None (0)'	System	08 Oct 2020 02:14:29
	System	08 Oct 2020 02:14:29

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:42:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-07T22:14:17', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '295b685c-49a4-41d1-b7f1-5ec312502100' User entered 'None (0)'	System	08 Oct 2020 02:14:29
	System	08 Oct 2020 02:14:29

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:42:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-07T22:14:18', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '295b685c-49a4-41d1-b7f1-5ec312502100' User entered 'None (0)'	System	08 Oct 2020 02:14:29
	System	08 Oct 2020 02:14:29

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:42:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-07T22:14:19', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '295b685c-49a4-41d1-b7f1-5ec312502100' User entered 'None (0)'	System	08 Oct 2020 02:14:29
	System	08 Oct 2020 02:14:29

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:42:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-07T22:14:20', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '295b685c-49a4-41d1-b7f1-5ec312502100' User entered 'None (0)'	System	08 Oct 2020 02:14:29
	System	08 Oct 2020 02:14:29

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:42:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-07T22:14:21', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '295b685c-49a4-41d1-b7f1-5ec312502100' User entered 'None (0)'	System	08 Oct 2020 02:14:29
	System	08 Oct 2020 02:14:29

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-07T22:14:25', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '295b685c-49a4-41d1-b7f1-5ec312502100' User entered 'No (N)'	System	08 Oct 2020 02:14:29
	System	08 Oct 2020 02:14:29

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:42:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-10-07T22:14:27', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '295b685c-49a4-41d1-b7f1-5ec312502100' User entered '07 Oct 2020 22:14'	System	08 Oct 2020 02:14:29
	System	08 Oct 2020 02:14:29

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '07 Oct 2020 12:00'	System	01 Oct 2020 16:45:52

US3432580

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '08 Oct 2020 11:59'	System	01 Oct 2020 16:45:52

US3432580

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:29:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 12:57:48

US3432580

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:29:14
User entered '8 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 12:57:48

US3432580

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:29:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Oct 2020 12:57:48

US3432580

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:29:14
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 12:57:48

US3432580

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:42:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:06:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 12:58:43

US3432580

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:42:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered '1'	System	08 Oct 2020 12:58:43

US3432580

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:29:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 14:13:35

US3432580

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:29:31
User entered '15 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 14:13:35

US3432580

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:29:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	15 Oct 2020 14:13:35

US3432580

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 16:29:31
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 14:13:35

US3432580

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:42:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 20:06:35
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 14:14:24

US3432580

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:42:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered 'I'	System	15 Oct 2020 14:14:24

US3432580

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:23:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Oct 2020 13:56:09

US3432580

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:23:00
User entered '22 Oct 2020'	(b) (4), (b) (6)	22 Oct 2020 13:56:09

US3432580

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:23:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Oct 2020 13:56:09

US3432580

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:23:00
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 13:56:09

US3432580

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:42:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:23:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Oct 2020 14:13:53

US3432580

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:42:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered 'I'	System	22 Oct 2020 14:13:53

US3432580

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:42:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:33:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 18:31:31

US3432580

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:33:46
User entered '5 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 18:31:31

US3432580

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:42:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:33:46
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	05 Nov 2020 18:31:31

US3432580

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:42:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered 'VISIT2'	System	05 Nov 2020 18:31:31

US3432580

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	05 Nov 2020 19:15:56

US3432580

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:34:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 19:15:56

US3432580

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:34:46
User entered '5 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 19:15:56

US3432580

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:38

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:34:46
User entered '12:23'	(b) (4), (b) (6)	05 Nov 2020 19:15:56

US3432580

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered '5 Nov 2020 12:23'	System	05 Nov 2020 19:15:56

US3432580

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:38

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:34:46
User entered '37.1' C	(b) (4), (b) (6)	05 Nov 2020 19:15:56

US3432580

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:34:46
User entered 'Oral (Oral)'	(b) (4), (b) (6)	05 Nov 2020 19:15:56

US3432580

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:34:46
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 19:15:56

US3432580

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:34:46
User entered '89'	(b) (4), (b) (6)	05 Nov 2020 19:15:56

US3432580

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered 'bpm'	System	05 Nov 2020 19:15:56

US3432580

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:34:46
User entered '14'	(b) (4), (b) (6)	05 Nov 2020 19:15:56

US3432580

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered 'breaths/min'	System	05 Nov 2020 19:15:56

US3432580

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:34:46
User entered '119'	(b) (4), (b) (6)	05 Nov 2020 19:15:56

US3432580

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered 'mmHg'	System	05 Nov 2020 19:15:56

US3432580

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:34:46
User entered '076'	(b) (4), (b) (6)	05 Nov 2020 19:15:56

US3432580

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Aug 2021 22:42:38

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered 'mmHg'	System	05 Nov 2020 19:15:56

US3432580

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:38

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	05 Nov 2020 19:15:56

US3432580

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:34:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 19:15:56

US3432580

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:34:46
User entered '5 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 19:15:56

US3432580

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:34:46
User entered '13:51'	(b) (4), (b) (6)	05 Nov 2020 19:15:56

US3432580

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered '5 Nov 2020 13:51'	System	05 Nov 2020 19:15:56

US3432580

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:38

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:34:46
User entered '97.7' F	(b) (4), (b) (6)	05 Nov 2020 19:15:56

US3432580

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:34:46
User entered 'Other (Other)'	(b) (4), (b) (6)	05 Nov 2020 19:15:56

US3432580

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:34:46
User entered 'infrared'	(b) (4), (b) (6)	05 Nov 2020 19:15:56

US3432580

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:34:46
User entered '80'	(b) (4), (b) (6)	05 Nov 2020 19:15:56

US3432580

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered 'bpm'	System	05 Nov 2020 19:15:56

US3432580

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:34:46
User entered '14'	(b) (4), (b) (6)	05 Nov 2020 19:15:56

US3432580

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered 'breaths/min'	System	05 Nov 2020 19:15:56

US3432580

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:38

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:34:46
User entered '128'	(b) (4), (b) (6)	05 Nov 2020 19:15:56

US3432580

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered 'mmHg'	System	05 Nov 2020 19:15:56

US3432580

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:34:46
User entered '78'	(b) (4), (b) (6)	05 Nov 2020 19:15:56

US3432580

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Aug 2021 22:42:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered 'mmHg'	System	05 Nov 2020 19:15:56

US3432580

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:42:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:35:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 18:39:24

US3432580

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:42:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:35:21
User entered '5 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 18:39:24

US3432580

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:42:38

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:35:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 18:40:31

US3432580

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:42:38

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:35:34
User entered '5 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 18:40:31

US3432580

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:42:38

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:35:34
User entered 'Urine (URINE)'	(b) (4), (b) (6)	05 Nov 2020 18:40:31

US3432580

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:42:38

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:35:34
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	05 Nov 2020 18:40:31

US3432580

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:42:38

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:35:34
User closed query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date and time has been recorded. Kindly update accordingly.' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 07:36:46
Query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date and time has been recorded. Kindly update accordingly.' answered with 'updated' (Site from DM).	Monica Feeley (b) (4)	11 Nov 2020 16:43:28
User opened query 'Per CDM: Please note the FSH sample collected is answered as "NO" but the collection date and time has been recorded. Kindly update accordingly.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 15:40:25
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 18:40:31

US3432580

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:42:38

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:35:34
User entered empty; reason for change Data Entry Error	Monica Feeley (b) (4)	11 Nov 2020 16:43:20
User entered '5 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 18:40:31

US3432580

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:42:38

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:35:34
User entered empty; reason for change Data Entry Error	Monica Feeley (b) (4)	11 Nov 2020 16:43:20
User entered '12:51'	(b) (4), (b) (6)	05 Nov 2020 18:40:31

US3432580

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 11 Aug 2021 22:42:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered empty.	System	11 Nov 2020 16:43:20
User entered '5 Nov 2020 12:51'	System	05 Nov 2020 18:40:31

US3432580

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:42:38

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:35:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 18:42:16

US3432580

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:42:38

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:35:53
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:42:16

US3432580

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:35:53
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 18:42:16

US3432580

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:42:38

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered 'MRNA-1273 OR PLACEBO'	System	05 Nov 2020 18:42:16

US3432580

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:42:38

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:35:53
User entered '5 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 18:42:16

US3432580

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:42:38

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:35:53
User entered '13:20'	(b) (4), (b) (6)	05 Nov 2020 18:42:16

US3432580

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:42:38

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered '5 Nov 2020 13:20'	System	05 Nov 2020 18:42:16

US3432580

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:42:38

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:35:53
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	05 Nov 2020 18:42:16

US3432580

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:42:38

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:35:53
User entered 'ONCE'	System	05 Nov 2020 18:42:16

US3432580

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Aug 2021 22:42:38

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered 'INTRAMUSCULAR'	System	05 Nov 2020 18:42:16

US3432580

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:42:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:36:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 20:45:07

US3432580

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:42:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:36:00
User entered '5 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 20:45:07

US3432580

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:42:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:36:00
User entered '13:06'	(b) (4), (b) (6)	05 Nov 2020 20:45:07

US3432580

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:42:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered '5 Nov 2020 13:06'	System	05 Nov 2020 20:45:07

US3432580

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Aug 2021 22:42:38

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:36:03
User entered '5 Nov 2020'	(b) (4), (b) (6)	05 Nov 2020 20:45:22

US3432580

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:42:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	05 Nov 2020 20:45:22

US3432580

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:42:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:36:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 20:45:22

US3432580

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:42:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:36:03
User entered '13:09'	(b) (4), (b) (6)	05 Nov 2020 20:45:22

US3432580

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Aug 2021 22:42:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered '5 Nov 2020 13:09'	System	05 Nov 2020 20:45:22

US3432580

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:42:38

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	05 Nov 2020 20:45:22

US3432580

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:42:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:36:03
User entered 'No (N)'	(b) (4), (b) (6)	05 Nov 2020 20:45:22

US3432580

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:42:38

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:36:03
User entered empty.	(b) (4), (b) (6)	05 Nov 2020 20:45:22

US3432580

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Aug 2021 22:42:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered empty.	System	05 Nov 2020 20:45:22

US3432580

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:42:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:36:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Nov 2020 19:02:15

US3432580

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:42:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered 'I'	System	05 Nov 2020 19:02:15

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	05 Nov 2020 18:42:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-05T13:50:18', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '3ed6860e-d4c7-4466-ae0d-841f7892881b' User entered 'Yes (Y)'	System	05 Nov 2020 18:50:32
	System	05 Nov 2020 18:50:32

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-05T13:50:22', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '3ed6860e-d4c7-4466-ae0d-841f7892881b' User entered '97.7'	System	05 Nov 2020 18:50:32
	System	05 Nov 2020 18:50:32

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-05T13:50:25', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '3ed6860e-d4c7-4466-ae0d-841f7892881b' User entered 'No (N)'	System	05 Nov 2020 18:50:32
	System	05 Nov 2020 18:50:32

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-05T13:50:29', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '3ed6860e-d4c7-4466-ae0d-841f7892881b' User entered '05 Nov 2020 13:50'	System	05 Nov 2020 18:50:32
	System	05 Nov 2020 18:50:32

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '05 Nov 2020 13:40'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '05 Nov 2020 16:10'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	05 Nov 2020 18:42:16
User entered 'Day 1, after vaccination (at home)'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '05 Nov 2020 17:05'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '06 Nov 2020 11:59'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	05 Nov 2020 18:42:16
User entered 'Day 2'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:42:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-06T12:02:59', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '716fa432-7b58-473a-9106-d002c94ae194'	System	06 Nov 2020 17:05:22
User entered 'Yes (Y)'	System	06 Nov 2020 17:05:22

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:42:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-06T12:03:07', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '716fa432-7b58-473a-9106-d002c94ae194' User entered '99.2'	System	06 Nov 2020 17:05:22
	System	06 Nov 2020 17:05:22

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-06T12:03:12', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '716fa432-7b58-473a-9106-d002c94ae194'	System	06 Nov 2020 17:05:22
User entered 'Yes (Y)'	System	06 Nov 2020 17:05:22

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Reported on day 36 safety call and conmed' (Site from System).	(b) (4), (b) (6)	10 Dec 2020 07:04:16
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	(b) (4), (b) (6)	19 Nov 2020 14:16:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-06T12:03:18', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '716fa432-7b58-473a-9106-d002c94ae194'	System	06 Nov 2020 17:05:22
User entered '1'	System	06 Nov 2020 17:05:22

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:42:38

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-06T12:03:18', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '716fa432-7b58-473a-9106-d002c94ae194' User entered '0'	System	06 Nov 2020 17:05:22
	System	06 Nov 2020 17:05:22

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:42:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-06T12:03:22', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '716fa432-7b58-473a-9106-d002c94ae194' User entered '06 Nov 2020 12:03'	System	06 Nov 2020 17:05:22
	System	06 Nov 2020 17:05:22

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '06 Nov 2020 12:00'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '07 Nov 2020 11:59'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	05 Nov 2020 18:42:16
User entered 'Day 3'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:42:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-07T22:31:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '4e70f70e-5b3c-4d1f-b8ae-424cb149dd00' User entered 'Yes (Y)'	System	08 Nov 2020 03:31:14
	System	08 Nov 2020 03:31:14

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:42:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-07T22:31:06', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '4e70f70e-5b3c-4d1f-b8ae-424cb149dd00' User entered '98.1'	System	08 Nov 2020 03:31:14
	System	08 Nov 2020 03:31:14

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-07T22:31:09', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '4e70f70e-5b3c-4d1f-b8ae-424cb149dd00'	System	08 Nov 2020 03:31:14
User entered 'No (N)'	System	08 Nov 2020 03:31:14

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:42:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-07T22:31:13', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '4e70f70e-5b3c-4d1f-b8ae-424cb149dd00' User entered '07 Nov 2020 22:31'	System	08 Nov 2020 03:31:14
	System	08 Nov 2020 03:31:14

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '07 Nov 2020 12:00'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '08 Nov 2020 11:59'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	05 Nov 2020 18:42:16
User entered 'Day 4'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:42:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-09T06:33:33', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'ddbc6060-3ee7-49b7-8148-dca8491e1b46' User entered 'Yes (Y)'	System	09 Nov 2020 11:34:51
	System	09 Nov 2020 11:34:51

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:42:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-09T06:34:41', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'ddbc6060-3ee7-49b7-8148-dca8491e1b46' User entered '97.3'	System	09 Nov 2020 11:34:51
	System	09 Nov 2020 11:34:51

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-09T06:34:43', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'ddbc6060-3ee7-49b7-8148-dca8491e1b46' User entered 'No (N)'	System	09 Nov 2020 11:34:51
	System	09 Nov 2020 11:34:51

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:42:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-09T06:34:48', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'ddbc6060-3ee7-49b7-8148-dca8491e1b46' User entered '09 Nov 2020 06:34'	System	09 Nov 2020 11:34:51
	System	09 Nov 2020 11:34:51

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '08 Nov 2020 12:00'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '09 Nov 2020 11:59'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	05 Nov 2020 18:42:16
User entered 'Day 5'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:42:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-10T00:00:55', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '1a7c96e3-1039-4aef-a53d-4c4ee4a34c2c' User entered 'Yes (Y)'	System	10 Nov 2020 05:01:38
	System	10 Nov 2020 05:01:38

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:42:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-10T00:01:20', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '1a7c96e3-1039-4aef-a53d-4c4ee4a34c2c' User entered '97.5'	System	10 Nov 2020 05:01:38
	System	10 Nov 2020 05:01:38

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-10T00:01:23', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '1a7c96e3-1039-4aef-a53d-4c4ee4a34c2c'	System	10 Nov 2020 05:01:38
User entered 'No (N)'	System	10 Nov 2020 05:01:38

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:42:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-10T00:01:27', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '1a7c96e3-1039-4aef-a53d-4c4ee4a34c2c' User entered '10 Nov 2020 00:01'	System	10 Nov 2020 05:01:38
	System	10 Nov 2020 05:01:38

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '09 Nov 2020 12:00'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '10 Nov 2020 11:59'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	05 Nov 2020 18:42:16
User entered 'Day 6'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:42:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-11T09:44:39', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '86c1a63e-ba28-466a-8a21-5768d93c50d7' User entered 'Yes (Y)'	System	11 Nov 2020 14:44:51
	System	11 Nov 2020 14:44:51

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:42:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-11T09:44:43', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '86c1a63e-ba28-466a-8a21-5768d93c50d7' User entered '97.5'	System	11 Nov 2020 14:44:51
	System	11 Nov 2020 14:44:51

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-11T09:44:45', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '86c1a63e-ba28-466a-8a21-5768d93c50d7' User entered 'No (N)'	System	11 Nov 2020 14:44:51
	System	11 Nov 2020 14:44:51

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:42:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-11T09:44:49', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '86c1a63e-ba28-466a-8a21-5768d93c50d7' User entered '11 Nov 2020 09:44'	System	11 Nov 2020 14:44:51
	System	11 Nov 2020 14:44:51

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '10 Nov 2020 12:00'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '11 Nov 2020 11:59'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	05 Nov 2020 18:42:16
User entered 'Day 7'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:42:38

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-12T00:00:23', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '9f32a512-d69a-4442-8dee-02f931784931' User entered 'Yes (Y)'	System	12 Nov 2020 05:01:02
	System	12 Nov 2020 05:01:02

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:42:38

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-12T00:00:51', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '9f32a512-d69a-4442-8dee-02f931784931' User entered '97.8'	System	12 Nov 2020 05:01:02
	System	12 Nov 2020 05:01:02

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-12T00:00:53', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '9f32a512-d69a-4442-8dee-02f931784931' User entered 'No (N)'	System	12 Nov 2020 05:01:02
	System	12 Nov 2020 05:01:02

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:42:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-12T00:00:59', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '9f32a512-d69a-4442-8dee-02f931784931' User entered '12 Nov 2020 00:00'	System	12 Nov 2020 05:01:02
	System	12 Nov 2020 05:01:02

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '11 Nov 2020 12:00'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '12 Nov 2020 11:59'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	05 Nov 2020 18:42:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-05T13:50:35', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '0fc9816d-571b-4541-88cf-898fc289cbfc' User entered 'None (1)'	System	05 Nov 2020 18:50:53
	System	05 Nov 2020 18:50:53

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-05T13:50:38', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '0fc9816d-571b-4541-88cf-898fc289cbfc' User entered 'No (N)'	System	05 Nov 2020 18:50:53
	System	05 Nov 2020 18:50:53

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-05T13:50:41', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '0fc9816d-571b-4541-88cf-898fc289cbfc' User entered 'No (N)'	System	05 Nov 2020 18:50:53
	System	05 Nov 2020 18:50:53

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-05T13:50:44', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '0fc9816d-571b-4541-88cf-898fc289cbfc' User entered 'None (1)'	System	05 Nov 2020 18:50:53
	System	05 Nov 2020 18:50:53

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-05T13:50:47', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '0fc9816d-571b-4541-88cf-898fc289cbfc' User entered '05 Nov 2020 13:50'	System	05 Nov 2020 18:50:53
	System	05 Nov 2020 18:50:53

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '05 Nov 2020 13:40'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '05 Nov 2020 16:10'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	05 Nov 2020 18:42:16
User entered 'Day 1, after vaccination (at home)'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-05T17:40:36', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '8d471a43-ac57-4dfd-8b73-128d3f21ef28'	System	05 Nov 2020 22:40:50
User entered 'Does not interfere with activity (2)'	System	05 Nov 2020 22:40:50

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-05T17:40:38', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '8d471a43-ac57-4dfd-8b73-128d3f21ef28' User entered 'No (N)'	System	05 Nov 2020 22:40:50
	System	05 Nov 2020 22:40:50

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-05T17:40:40', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '8d471a43-ac57-4dfd-8b73-128d3f21ef28' User entered 'No (N)'	System	05 Nov 2020 22:40:50
	System	05 Nov 2020 22:40:50

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-05T17:40:46', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '8d471a43-ac57-4dfd-8b73-128d3f21ef28' User entered 'None (1)'	System	05 Nov 2020 22:40:50
	System	05 Nov 2020 22:40:50

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-05T17:40:48', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '8d471a43-ac57-4dfd-8b73-128d3f21ef28' User entered '05 Nov 2020 17:40'	System	05 Nov 2020 22:40:50
	System	05 Nov 2020 22:40:50

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '05 Nov 2020 17:05'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '06 Nov 2020 11:59'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	05 Nov 2020 18:42:16
User entered 'Day 2'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:42:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-06T12:02:01', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '02d6c8df-cbba-4c39-89d4-9f5dfd9418df' User entered 'Does not interfere with activity (2)'	System	06 Nov 2020 17:03:12
	System	06 Nov 2020 17:03:12

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:42:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-06T12:02:03', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '02d6c8df-cbba-4c39-89d4-9f5dfd9418df' User entered 'No (N)'	System	06 Nov 2020 17:03:12
	System	06 Nov 2020 17:03:12

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-06T12:02:04', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '02d6c8df-cbba-4c39-89d4-9f5dfd9418df' User entered 'No (N)'	System	06 Nov 2020 17:03:12
	System	06 Nov 2020 17:03:12

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:42:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-06T12:02:08', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '02d6c8df-cbba-4c39-89d4-9f5dfd9418df' User entered 'None (1)'	System	06 Nov 2020 17:03:12
	System	06 Nov 2020 17:03:12

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:42:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-06T12:02:11', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '02d6c8df-cbba-4c39-89d4-9f5dfd9418df' User entered '06 Nov 2020 12:02'	System	06 Nov 2020 17:03:12
	System	06 Nov 2020 17:03:12

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '06 Nov 2020 12:00'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '07 Nov 2020 11:59'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	05 Nov 2020 18:42:16
User entered 'Day 3'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:42:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-07T22:29:49', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '8b9a7d2c-0313-44c1-a9a7-4fcba9a0d523' User entered 'None (1)'	System	08 Nov 2020 03:30:27
	System	08 Nov 2020 03:30:27

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:42:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-07T22:29:53', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '8b9a7d2c-0313-44c1-a9a7-4fcba9a0d523' User entered 'No (N)'	System	08 Nov 2020 03:30:27
	System	08 Nov 2020 03:30:27

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-07T22:30:15', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '8b9a7d2c-0313-44c1-a9a7-4fcba9a0d523' User entered 'No (N)'	System	08 Nov 2020 03:30:27
	System	08 Nov 2020 03:30:27

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:42:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-07T22:30:18', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '8b9a7d2c-0313-44c1-a9a7-4fcba9a0d523'	System	08 Nov 2020 03:30:27
User entered 'None (1)'	System	08 Nov 2020 03:30:27

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:42:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-07T22:30:22', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '8b9a7d2c-0313-44c1-a9a7-4fcba9a0d523' User entered '07 Nov 2020 22:30'	System	08 Nov 2020 03:30:27
	System	08 Nov 2020 03:30:27

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '07 Nov 2020 12:00'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '08 Nov 2020 11:59'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	05 Nov 2020 18:42:16
User entered 'Day 4'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:42:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-09T06:33:18', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '52f08000-b800-4159-86ca-de67510daaa7'	System	09 Nov 2020 11:33:31
User entered 'None (1)'	System	09 Nov 2020 11:33:31

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-09T06:33:20', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '52f08000-b800-4159-86ca-de67510daaa7'	System	09 Nov 2020 11:33:31
User entered 'No (N)'	System	09 Nov 2020 11:33:31

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-09T06:33:23', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '52f08000-b800-4159-86ca-de67510daaa7' User entered 'No (N)'	System	09 Nov 2020 11:33:31
	System	09 Nov 2020 11:33:31

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:42:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-09T06:33:25', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '52f08000-b800-4159-86ca-de67510daaa7' User entered 'None (1)'	System	09 Nov 2020 11:33:31
	System	09 Nov 2020 11:33:31

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:42:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-09T06:33:27', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '52f08000-b800-4159-86ca-de67510daaa7' User entered '09 Nov 2020 06:33'	System	09 Nov 2020 11:33:31
	System	09 Nov 2020 11:33:31

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '08 Nov 2020 12:00'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '09 Nov 2020 11:59'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	05 Nov 2020 18:42:16
User entered 'Day 5'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:42:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-10T00:00:23', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '95c41d1c-f0f3-42e5-9fb3-bc635bea9d25'	System	10 Nov 2020 05:00:37
User entered 'None (1)'	System	10 Nov 2020 05:00:37

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:42:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-10T00:00:25', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '95c41d1c-f0f3-42e5-9fb3-bc635bea9d25'	System	10 Nov 2020 05:00:37
User entered 'No (N)'	System	10 Nov 2020 05:00:37

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-10T00:00:26', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '95c41d1c-f0f3-42e5-9fb3-bc635bea9d25'	System	10 Nov 2020 05:00:37
User entered 'No (N)'	System	10 Nov 2020 05:00:37

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:42:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-10T00:00:28', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '95c41d1c-f0f3-42e5-9fb3-bc635bea9d25'	System	10 Nov 2020 05:00:37
User entered 'None (1)'	System	10 Nov 2020 05:00:37

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:42:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-10T00:00:30', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '95c41d1c-f0f3-42e5-9fb3-bc635bea9d25' User entered '10 Nov 2020 00:00'	System	10 Nov 2020 05:00:37
	System	10 Nov 2020 05:00:37

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '09 Nov 2020 12:00'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '10 Nov 2020 11:59'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	05 Nov 2020 18:42:16
User entered 'Day 6'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:42:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-11T09:44:03', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '2bc6970d-0e05-46d9-a103-0b118b837fe7' User entered 'None (1)'	System	11 Nov 2020 14:44:13
	System	11 Nov 2020 14:44:13

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:42:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-11T09:44:05', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '2bc6970d-0e05-46d9-a103-0b118b837fe7' User entered 'No (N)'	System	11 Nov 2020 14:44:13
	System	11 Nov 2020 14:44:13

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-11T09:44:06', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '2bc6970d-0e05-46d9-a103-0b118b837fe7' User entered 'No (N)'	System	11 Nov 2020 14:44:13
	System	11 Nov 2020 14:44:13

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:42:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-11T09:44:08', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '2bc6970d-0e05-46d9-a103-0b118b837fe7' User entered 'None (1)'	System	11 Nov 2020 14:44:13
	System	11 Nov 2020 14:44:13

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:42:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-11T09:44:11', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '2bc6970d-0e05-46d9-a103-0b118b837fe7' User entered '11 Nov 2020 09:44'	System	11 Nov 2020 14:44:13
	System	11 Nov 2020 14:44:13

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '10 Nov 2020 12:00'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '11 Nov 2020 11:59'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	05 Nov 2020 18:42:16
User entered 'Day 7'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:42:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-11T23:59:36', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'bf29f62c-958b-4b3f-9678-a055cce4e8dd'	System	12 Nov 2020 04:59:47
User entered 'None (1)'	System	12 Nov 2020 04:59:47

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:42:38

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-11T23:59:38', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'bf29f62c-958b-4b3f-9678-a055cce4e8dd'	System	12 Nov 2020 04:59:47
User entered 'No (N)'	System	12 Nov 2020 04:59:47

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-11T23:59:41', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'bf29f62c-958b-4b3f-9678-a055cce4e8dd' User entered 'No (N)'	System	12 Nov 2020 04:59:47
	System	12 Nov 2020 04:59:47

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:42:38

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-11T23:59:42', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'bf29f62c-958b-4b3f-9678-a055cce4e8dd'	System	12 Nov 2020 04:59:47
User entered 'None (1)'	System	12 Nov 2020 04:59:47

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:42:38

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-11T23:59:45', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'bf29f62c-958b-4b3f-9678-a055cce4e8dd' User entered '11 Nov 2020 23:59'	System	12 Nov 2020 04:59:47
	System	12 Nov 2020 04:59:47

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '11 Nov 2020 12:00'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '12 Nov 2020 11:59'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	05 Nov 2020 18:42:16
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-05T13:50:51', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'b736ba5c-cbb4-4379-8c7c-6e084e5daf7f' User entered 'None (0)'	System	05 Nov 2020 18:51:12
	System	05 Nov 2020 18:51:12

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-05T13:50:54', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'b736ba5c-cbb4-4379-8c7c-6e084e5daf7f' User entered 'None (0)'	System	05 Nov 2020 18:51:12
	System	05 Nov 2020 18:51:12

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-05T13:50:57', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'b736ba5c-cbb4-4379-8c7c-6e084e5daf7f' User entered 'None (0)'	System	05 Nov 2020 18:51:12
	System	05 Nov 2020 18:51:12

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-05T13:50:59', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'b736ba5c-cbb4-4379-8c7c-6e084e5daf7f' User entered 'None (0)'	System	05 Nov 2020 18:51:12
	System	05 Nov 2020 18:51:12

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-05T13:51:01', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'b736ba5c-cbb4-4379-8c7c-6e084e5daf7f' User entered 'None (0)'	System	05 Nov 2020 18:51:12
	System	05 Nov 2020 18:51:12

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-05T13:51:03', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'b736ba5c-cbb4-4379-8c7c-6e084e5daf7f' User entered 'None (0)'	System	05 Nov 2020 18:51:12
	System	05 Nov 2020 18:51:12

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-05T13:51:06', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'b736ba5c-cbb4-4379-8c7c-6e084e5daf7f' User entered 'No (N)'	System	05 Nov 2020 18:51:12
	System	05 Nov 2020 18:51:12

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-05T13:51:09', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'b736ba5c-cbb4-4379-8c7c-6e084e5daf7f' User entered '05 Nov 2020 13:51'	System	05 Nov 2020 18:51:12
	System	05 Nov 2020 18:51:12

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '05 Nov 2020 13:40'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '05 Nov 2020 16:10'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	05 Nov 2020 18:42:16
User entered 'Day 1, after vaccination (at home)'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-05T17:40:51', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '2ad309be-e731-4acf-8db4-04b54f1bdfab' User entered 'None (0)'	System	05 Nov 2020 22:41:05
	System	05 Nov 2020 22:41:05

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-05T17:40:52', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '2ad309be-e731-4acf-8db4-04b54f1bdfab' User entered 'None (0)'	System	05 Nov 2020 22:41:05
	System	05 Nov 2020 22:41:05

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-05T17:40:54', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '2ad309be-e731-4acf-8db4-04b54f1bdfab' User entered 'None (0)'	System	05 Nov 2020 22:41:05
	System	05 Nov 2020 22:41:05

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-05T17:40:55', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '2ad309be-e731-4acf-8db4-04b54f1bdfab' User entered 'None (0)'	System	05 Nov 2020 22:41:05
	System	05 Nov 2020 22:41:05

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-05T17:40:56', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '2ad309be-e731-4acf-8db4-04b54f1bdfab' User entered 'None (0)'	System	05 Nov 2020 22:41:05
	System	05 Nov 2020 22:41:05

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-05T17:40:58', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '2ad309be-e731-4acf-8db4-04b54f1bdfab' User entered 'None (0)'	System	05 Nov 2020 22:41:05
	System	05 Nov 2020 22:41:05

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-05T17:41:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '2ad309be-e731-4acf-8db4-04b54f1bdfab' User entered 'No (N)'	System	05 Nov 2020 22:41:05
	System	05 Nov 2020 22:41:05

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-05T17:41:02', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '2ad309be-e731-4acf-8db4-04b54f1bdfab' User entered '05 Nov 2020 17:41'	System	05 Nov 2020 22:41:05
	System	05 Nov 2020 22:41:05

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '05 Nov 2020 17:05'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '06 Nov 2020 11:59'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	05 Nov 2020 18:42:16
User entered 'Day 2'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:42:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-06T12:02:23', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '29960014-39d7-4947-9cd0-07bbdb2c4259'	System	06 Nov 2020 17:04:25
User entered 'No interference with activity (1)'	System	06 Nov 2020 17:04:25

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:42:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-06T12:02:27', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '29960014-39d7-4947-9cd0-07bbdb2c4259'	System	06 Nov 2020 17:04:25
User entered 'No interference with activity (1)'	System	06 Nov 2020 17:04:25

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:42:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-06T12:02:33', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '29960014-39d7-4947-9cd0-07bbdb2c4259'	System	06 Nov 2020 17:04:25
User entered 'Some interference with activity (2)'	System	06 Nov 2020 17:04:25

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:42:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-06T12:02:40', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '29960014-39d7-4947-9cd0-07bbdb2c4259' User entered 'None (0)'	System	06 Nov 2020 17:04:25
	System	06 Nov 2020 17:04:25

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:42:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-06T12:02:42', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '29960014-39d7-4947-9cd0-07bbdb2c4259' User entered 'None (0)'	System	06 Nov 2020 17:04:25
	System	06 Nov 2020 17:04:25

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:42:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-06T12:02:43', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '29960014-39d7-4947-9cd0-07bbdb2c4259' User entered 'None (0)'	System	06 Nov 2020 17:04:25
	System	06 Nov 2020 17:04:25

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-06T12:02:46', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '29960014-39d7-4947-9cd0-07bbdb2c4259' User entered 'No (N)'	System	06 Nov 2020 17:04:25
	System	06 Nov 2020 17:04:25

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:42:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-06T12:02:52', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '29960014-39d7-4947-9cd0-07bbdb2c4259' User entered '06 Nov 2020 12:02'	System	06 Nov 2020 17:04:25
	System	06 Nov 2020 17:04:25

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '06 Nov 2020 12:00'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '07 Nov 2020 11:59'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	05 Nov 2020 18:42:16
User entered 'Day 3'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:42:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-07T22:30:27', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'bd1f8485-5225-41d4-b3c1-d7add1ec5662' User entered 'None (0)'	System	08 Nov 2020 03:30:53
	System	08 Nov 2020 03:30:53

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:42:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-07T22:30:30', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'bd1f8485-5225-41d4-b3c1-d7add1ec5662' User entered 'None (0)'	System	08 Nov 2020 03:30:53
	System	08 Nov 2020 03:30:53

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:42:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-07T22:30:38', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'bd1f8485-5225-41d4-b3c1-d7add1ec5662' User entered 'None (0)'	System	08 Nov 2020 03:30:53
	System	08 Nov 2020 03:30:53

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:42:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-07T22:30:40', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'bd1f8485-5225-41d4-b3c1-d7add1ec5662' User entered 'None (0)'	System	08 Nov 2020 03:30:53
	System	08 Nov 2020 03:30:53

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:42:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-07T22:30:41', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'bd1f8485-5225-41d4-b3c1-d7add1ec5662' User entered 'None (0)'	System	08 Nov 2020 03:30:53
	System	08 Nov 2020 03:30:53

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:42:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-07T22:30:43', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'bd1f8485-5225-41d4-b3c1-d7add1ec5662' User entered 'None (0)'	System	08 Nov 2020 03:30:53
	System	08 Nov 2020 03:30:53

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-07T22:30:48', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'bd1f8485-5225-41d4-b3c1-d7add1ec5662' User entered 'No (N)'	System	08 Nov 2020 03:30:53
	System	08 Nov 2020 03:30:53

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:42:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-07T22:30:51', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'bd1f8485-5225-41d4-b3c1-d7add1ec5662' User entered '07 Nov 2020 22:30'	System	08 Nov 2020 03:30:53
	System	08 Nov 2020 03:30:53

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '07 Nov 2020 12:00'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '08 Nov 2020 11:59'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	05 Nov 2020 18:42:16
User entered 'Day 4'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:42:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-09T06:33:03', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '6dff8db1-5dec-46c0-b90c-4e423bd4577d' User entered 'None (0)'	System	09 Nov 2020 11:33:17
	System	09 Nov 2020 11:33:17

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:42:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-09T06:33:04', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '6dff8db1-5dec-46c0-b90c-4e423bd4577d' User entered 'None (0)'	System	09 Nov 2020 11:33:17
	System	09 Nov 2020 11:33:17

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:42:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-09T06:33:06', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '6dff8db1-5dec-46c0-b90c-4e423bd4577d' User entered 'None (0)'	System	09 Nov 2020 11:33:17
	System	09 Nov 2020 11:33:17

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:42:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-09T06:33:08', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '6dff8db1-5dec-46c0-b90c-4e423bd4577d' User entered 'None (0)'	System	09 Nov 2020 11:33:17
	System	09 Nov 2020 11:33:17

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:42:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-09T06:33:09', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '6dff8db1-5dec-46c0-b90c-4e423bd4577d' User entered 'None (0)'	System	09 Nov 2020 11:33:17
	System	09 Nov 2020 11:33:17

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:42:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-09T06:33:10', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '6dff8db1-5dec-46c0-b90c-4e423bd4577d' User entered 'None (0)'	System	09 Nov 2020 11:33:17
	System	09 Nov 2020 11:33:17

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-09T06:33:12', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '6dff8db1-5dec-46c0-b90c-4e423bd4577d' User entered 'No (N)'	System	09 Nov 2020 11:33:17
	System	09 Nov 2020 11:33:17

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:42:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-09T06:33:15', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '6dff8db1-5dec-46c0-b90c-4e423bd4577d' User entered '09 Nov 2020 06:33'	System	09 Nov 2020 11:33:17
	System	09 Nov 2020 11:33:17

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '08 Nov 2020 12:00'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '09 Nov 2020 11:59'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	05 Nov 2020 18:42:16
User entered 'Day 5'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:42:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-10T00:00:33', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '640e4d25-5a98-4c11-9cd2-cb96ba2bbd5f' User entered 'None (0)'	System	10 Nov 2020 05:00:55
	System	10 Nov 2020 05:00:55

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:42:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-10T00:00:36', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '640e4d25-5a98-4c11-9cd2-cb96ba2bbd5f' User entered 'None (0)'	System	10 Nov 2020 05:00:55
	System	10 Nov 2020 05:00:55

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:42:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-10T00:00:38', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '640e4d25-5a98-4c11-9cd2-cb96ba2bbd5f' User entered 'None (0)'	System	10 Nov 2020 05:00:55
	System	10 Nov 2020 05:00:55

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:42:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-10T00:00:39', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '640e4d25-5a98-4c11-9cd2-cb96ba2bbd5f' User entered 'None (0)'	System	10 Nov 2020 05:00:55
	System	10 Nov 2020 05:00:55

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:42:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-10T00:00:41', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '640e4d25-5a98-4c11-9cd2-cb96ba2bbd5f' User entered 'None (0)'	System	10 Nov 2020 05:00:55
	System	10 Nov 2020 05:00:55

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:42:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-10T00:00:43', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '640e4d25-5a98-4c11-9cd2-cb96ba2bbd5f' User entered 'None (0)'	System	10 Nov 2020 05:00:55
	System	10 Nov 2020 05:00:55

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-10T00:00:45', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '640e4d25-5a98-4c11-9cd2-cb96ba2bbd5f' User entered 'No (N)'	System	10 Nov 2020 05:00:55
	System	10 Nov 2020 05:00:55

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:42:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-10T00:00:50', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '640e4d25-5a98-4c11-9cd2-cb96ba2bbd5f' User entered '10 Nov 2020 00:00'	System	10 Nov 2020 05:00:55
	System	10 Nov 2020 05:00:55

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '09 Nov 2020 12:00'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '10 Nov 2020 11:59'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	05 Nov 2020 18:42:16
User entered 'Day 6'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:42:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-11T09:44:15', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '6c1e6445-907b-487a-a334-2e95eb278235' User entered 'None (0)'	System	11 Nov 2020 14:44:37
	System	11 Nov 2020 14:44:37

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:42:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-11T09:44:16', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '6c1e6445-907b-487a-a334-2e95eb278235' User entered 'None (0)'	System	11 Nov 2020 14:44:37
	System	11 Nov 2020 14:44:37

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:42:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-11T09:44:17', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '6c1e6445-907b-487a-a334-2e95eb278235' User entered 'None (0)'	System	11 Nov 2020 14:44:37
	System	11 Nov 2020 14:44:37

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:42:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-11T09:44:19', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '6c1e6445-907b-487a-a334-2e95eb278235' User entered 'None (0)'	System	11 Nov 2020 14:44:37
	System	11 Nov 2020 14:44:37

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:42:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-11T09:44:20', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '6c1e6445-907b-487a-a334-2e95eb278235' User entered 'None (0)'	System	11 Nov 2020 14:44:37
	System	11 Nov 2020 14:44:37

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:42:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-11T09:44:21', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '6c1e6445-907b-487a-a334-2e95eb278235' User entered 'None (0)'	System	11 Nov 2020 14:44:37
	System	11 Nov 2020 14:44:37

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-11T09:44:32', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '6c1e6445-907b-487a-a334-2e95eb278235' User entered 'No (N)'	System	11 Nov 2020 14:44:37
	System	11 Nov 2020 14:44:37

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:42:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-11T09:44:35', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '6c1e6445-907b-487a-a334-2e95eb278235' User entered '11 Nov 2020 09:44'	System	11 Nov 2020 14:44:37
	System	11 Nov 2020 14:44:37

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '10 Nov 2020 12:00'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '11 Nov 2020 11:59'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
Data entry locked.	System	05 Nov 2020 18:42:16
User entered 'Day 7'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:42:38

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-11T23:59:48', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '9b5f5747-1e5b-4c40-b0e7-335103b357ec' User entered 'None (0)'	System	12 Nov 2020 05:00:19
	System	12 Nov 2020 05:00:19

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:42:38

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-11T23:59:50', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '9b5f5747-1e5b-4c40-b0e7-335103b357ec' User entered 'None (0)'	System	12 Nov 2020 05:00:19
	System	12 Nov 2020 05:00:19

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:42:38

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-11T23:59:52', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '9b5f5747-1e5b-4c40-b0e7-335103b357ec' User entered 'None (0)'	System	12 Nov 2020 05:00:19
	System	12 Nov 2020 05:00:19

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:42:38

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-12T00:00:04', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '9b5f5747-1e5b-4c40-b0e7-335103b357ec' User entered 'None (0)'	System	12 Nov 2020 05:00:19
	System	12 Nov 2020 05:00:19

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:42:38

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-12T00:00:06', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '9b5f5747-1e5b-4c40-b0e7-335103b357ec' User entered 'None (0)'	System	12 Nov 2020 05:00:19
	System	12 Nov 2020 05:00:19

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:42:38

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-12T00:00:08', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '9b5f5747-1e5b-4c40-b0e7-335103b357ec' User entered 'None (0)'	System	12 Nov 2020 05:00:19
	System	12 Nov 2020 05:00:19

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-12T00:00:10', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '9b5f5747-1e5b-4c40-b0e7-335103b357ec' User entered 'No (N)'	System	12 Nov 2020 05:00:19
	System	12 Nov 2020 05:00:19

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:42:38

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-11-12T00:00:17', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '9b5f5747-1e5b-4c40-b0e7-335103b357ec' User entered '12 Nov 2020 00:00'	System	12 Nov 2020 05:00:19
	System	12 Nov 2020 05:00:19

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:42:38

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '11 Nov 2020 12:00'	System	05 Nov 2020 18:42:16

US3432580

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 11 Aug 2021 22:42:38

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 23:28:34
User entered '12 Nov 2020 11:59'	System	05 Nov 2020 18:42:16

US3432580

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:36:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 14:32:28

US3432580

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:36:58
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 14:32:28

US3432580

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:36:58
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	12 Nov 2020 14:32:28

US3432580

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:36:58
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 14:32:28

US3432580

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:42:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:37:00
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 14:32:38

US3432580

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:42:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered 'I'	System	12 Nov 2020 14:32:38

US3432580

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:37:53
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	19 Nov 2020 19:10:52

US3432580

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:37:53
User entered '19 Nov 2020'	Kathleen Garvey (b) (4)	19 Nov 2020 19:10:52

US3432580

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:37:53
User entered 'Contact Made (CONTACT MADE)'	Kathleen Garvey (b) (4)	19 Nov 2020 19:10:52

US3432580

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:37:53
User entered empty.	Kathleen Garvey (b) (4)	19 Nov 2020 19:10:52

US3432580

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:42:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:37:56
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	19 Nov 2020 19:11:06

US3432580

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:42:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered 'I'	System	19 Nov 2020 19:11:06

US3432580

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:38:27
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	27 Nov 2020 15:26:41

US3432580

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:38:27
User entered '27 Nov 2020'	Kathleen Garvey (b) (4)	27 Nov 2020 15:26:41

US3432580

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:38:27
User entered 'Contact Made (CONTACT MADE)'	Kathleen Garvey (b) (4)	27 Nov 2020 15:26:41

US3432580

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:38:27
User entered empty.	Kathleen Garvey (b) (4)	27 Nov 2020 15:26:41

US3432580

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:42:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:38:30
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	27 Nov 2020 15:26:59

US3432580

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:42:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered 'I'	System	27 Nov 2020 15:26:59

US3432580

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:42:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:23:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Dec 2020 17:46:19

US3432580

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:23:27
User entered '3 Dec 2020'	(b) (4), (b) (6)	03 Dec 2020 17:46:19

US3432580

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:42:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:23:27
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	03 Dec 2020 17:46:19

US3432580

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Aug 2021 22:42:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered 'VISIT3'	System	03 Dec 2020 17:46:19

US3432580

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:23:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Dec 2020 17:46:56

US3432580

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:23:42
User entered '3 Dec 2020'	(b) (4), (b) (6)	03 Dec 2020 17:46:56

US3432580

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:23:42
User entered '12:23'	(b) (4), (b) (6)	03 Dec 2020 17:46:56

US3432580

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered '3 Dec 2020 12:23'	System	03 Dec 2020 17:46:56

US3432580

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:23:42
User entered '96.8' F	(b) (4), (b) (6)	03 Dec 2020 17:46:56

US3432580

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:23:42
User entered 'Other (Other)'	(b) (4), (b) (6)	03 Dec 2020 17:46:56

US3432580

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:23:42
User entered 'Infrared'	(b) (4), (b) (6)	03 Dec 2020 17:46:56

US3432580

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:23:42
User entered '88'	(b) (4), (b) (6)	03 Dec 2020 17:46:56

US3432580

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered 'bpm'	System	03 Dec 2020 17:46:56

US3432580

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:23:42
User entered '16'	(b) (4), (b) (6)	03 Dec 2020 17:46:56

US3432580

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered 'breaths/min'	System	03 Dec 2020 17:46:56

US3432580

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:23:42
User entered '128'	(b) (4), (b) (6)	03 Dec 2020 17:46:56

US3432580

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered 'mmHg'	System	03 Dec 2020 17:46:56

US3432580

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:23:42
User entered '81'	(b) (4), (b) (6)	03 Dec 2020 17:46:56

US3432580

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered 'mmHg'	System	03 Dec 2020 17:46:56

US3432580

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20

US3432580

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Aug 2021 22:42:38

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20

US3432580

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:42:38

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:23:48
User entered 'No (N)'	(b) (4), (b) (6)	03 Dec 2020 17:47:12

US3432580

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Aug 2021 22:42:38

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:23:48
User entered empty.	(b) (4), (b) (6)	03 Dec 2020 17:47:12

US3432580

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:42:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:23:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Dec 2020 17:47:26

US3432580

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:23:59
User entered '3 Dec 2020'	(b) (4), (b) (6)	03 Dec 2020 17:47:26

US3432580

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:42:38

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:23:59
User entered '12:32'	(b) (4), (b) (6)	03 Dec 2020 17:47:26

US3432580

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:42:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered '3 Dec 2020 12:32'	System	03 Dec 2020 17:47:26

US3432580

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:42:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:24:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Dec 2020 17:47:33

US3432580

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:42:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered '1'	System	03 Dec 2020 17:47:33

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-12-01T06:14:35', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'e2c0c7d9-e485-4f03-8716-517f0a15e066'	System	01 Dec 2020 11:14:47
User entered 'No (N)'	System	01 Dec 2020 11:14:47

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

Have you been exposed to someone with 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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-12-01T06:14:41', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'e2c0c7d9-e485-4f03-8716-517f0a15e066'	System	01 Dec 2020 11:14:47
User entered 'No (N)'	System	01 Dec 2020 11:14:47

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-12-01T06:14:44', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'e2c0c7d9-e485-4f03-8716-517f0a15e066' User entered '01 Dec 2020 06:14:44'	System	01 Dec 2020 11:14:47
	System	01 Dec 2020 11:14:47

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-12-07T12:00:38', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'f2b09676-2a94-4285-8860-62e60596f189' User entered 'No (N)'	System	07 Dec 2020 17:00:52
	System	07 Dec 2020 17:00:52

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

Have you been exposed to someone with 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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-12-07T12:00:40', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'f2b09676-2a94-4285-8860-62e60596f189' User entered 'No (N)'	System	07 Dec 2020 17:00:52

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-12-07T12:00:43', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'f2b09676-2a94-4285-8860-62e60596f189' User entered '07 Dec 2020 12:00:43'	System	07 Dec 2020 17:00:52
	System	07 Dec 2020 17:00:52

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-12-12T07:21:41', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '3b383805-a673-4a28-a2f2-e77213fb32d5'	System	12 Dec 2020 12:21:53
User entered 'No (N)'	System	12 Dec 2020 12:21:53

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Have you been exposed to someone with 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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-12-12T07:21:48', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '3b383805-a673-4a28-a2f2-e77213fb32d5'	System	12 Dec 2020 12:21:53
User entered 'No (N)'	System	12 Dec 2020 12:21:53

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-12-12T07:21:51', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '3b383805-a673-4a28-a2f2-e77213fb32d5' User entered '12 Dec 2020 07:21:51'	System	12 Dec 2020 12:21:53
	System	12 Dec 2020 12:21:53

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-12-21T12:12:22', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '31a91d05-c5ba-42cc-8d96-3a417fdb7a59'	System	21 Dec 2020 17:12:37
User entered 'No (N)'	System	21 Dec 2020 17:12:37

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

Have you been exposed to someone with 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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-12-21T12:12:25', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '31a91d05-c5ba-42cc-8d96-3a417fdb7a59'	System	21 Dec 2020 17:12:37
User entered 'No (N)'	System	21 Dec 2020 17:12:37

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-12-21T12:12:31', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '31a91d05-c5ba-42cc-8d96-3a417fdb7a59' User entered '21 Dec 2020 12:12:31'	System	21 Dec 2020 17:12:37
	System	21 Dec 2020 17:12:37

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-12-26T00:02:39', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '2273f7f3-ce90-418c-96b2-968c62d4cea0' User entered 'No (N)'	System	26 Dec 2020 05:03:02

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Have you been exposed to someone with 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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-12-26T00:02:41', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '2273f7f3-ce90-418c-96b2-968c62d4cea0' User entered 'No (N)'	System	26 Dec 2020 05:03:02

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2020-12-26T00:02:45', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '2273f7f3-ce90-418c-96b2-968c62d4cea0' User entered '26 Dec 2020 00:02:45'	System	26 Dec 2020 05:03:02
	System	26 Dec 2020 05:03:02

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-01-05T18:04:02', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '6aab5897-c0af-4254-84a8-58e85464e61e' User entered 'No (N)'	System	05 Jan 2021 23:04:22
	System	05 Jan 2021 23:04:22

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

Have you been exposed to someone with 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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-01-05T18:04:04', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '6aab5897-c0af-4254-84a8-58e85464e61e'	System	05 Jan 2021 23:04:22
User entered 'No (N)'	System	05 Jan 2021 23:04:22

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-01-05T18:04:14', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '6aab5897-c0af-4254-84a8-58e85464e61e' User entered '05 Jan 2021 18:04:14'	System	05 Jan 2021 23:04:22
	System	05 Jan 2021 23:04:22

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-01-11T12:00:26', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'f6b34ad4-d16b-47f8-89be-bd1c46e3b2f5'	System	12 Jan 2021 23:05:12
User entered 'No (N)'	System	12 Jan 2021 23:05:12

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

Have you been exposed to someone with 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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-01-11T12:00:27', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'f6b34ad4-d16b-47f8-89be-bd1c46e3b2f5'	System	12 Jan 2021 23:05:12
User entered 'No (N)'	System	12 Jan 2021 23:05:12

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-01-11T12:00:30', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'f6b34ad4-d16b-47f8-89be-bd1c46e3b2f5' User entered '11 Jan 2021 12:00:30'	System	12 Jan 2021 23:05:12
	System	12 Jan 2021 23:05:12

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-01-18T12:06:43', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '7b2fabb8-6ca4-44d2-aa9b-54a15bae89a0'	System	18 Jan 2021 17:06:49
User entered 'No (N)'	System	18 Jan 2021 17:06:49

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Have you been exposed to someone with 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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-01-18T12:06:44', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '7b2fabb8-6ca4-44d2-aa9b-54a15bae89a0'	System	18 Jan 2021 17:06:49
User entered 'No (N)'	System	18 Jan 2021 17:06:49

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-01-18T12:06:46', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '7b2fabb8-6ca4-44d2-aa9b-54a15bae89a0' User entered '18 Jan 2021 12:06:46'	System	18 Jan 2021 17:06:49
	System	18 Jan 2021 17:06:49

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-01-25T12:01:19', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '6bad4887-5612-4021-921a-00965049eade' User entered 'No (N)'	System	25 Jan 2021 17:04:29

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

Have you been exposed to someone with 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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-01-25T12:01:22', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '6bad4887-5612-4021-921a-00965049eade' User entered 'No (N)'	System	25 Jan 2021 17:04:29

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-01-25T12:01:25', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '6bad4887-5612-4021-921a-00965049eade' User entered '25 Jan 2021 12:01:25'	System	25 Jan 2021 17:04:29

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-01-30T00:01:25', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '7883f2db-6cfb-476c-ba91-c8318890b444'	System	30 Jan 2021 05:02:08
User entered 'No (N)'	System	30 Jan 2021 05:02:08

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Have you been exposed to someone with 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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-01-30T00:01:26', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '7883f2db-6cfb-476c-ba91-c8318890b444'	System	30 Jan 2021 05:02:08
User entered 'No (N)'	System	30 Jan 2021 05:02:08

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-01-30T00:01:29', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '7883f2db-6cfb-476c-ba91-c8318890b444' User entered '30 Jan 2021 00:01:29'	System	30 Jan 2021 05:02:08
	System	30 Jan 2021 05:02:08

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-02-09T17:59:35', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'ada0e8de-bfb3-44e9-a718-c6570e935944'	System	09 Feb 2021 22:59:42
User entered 'No (N)'	System	09 Feb 2021 22:59:42

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

Have you been exposed to someone with 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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-02-09T17:59:37', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'ada0e8de-bfb3-44e9-a718-c6570e935944'	System	09 Feb 2021 22:59:42
User entered 'No (N)'	System	09 Feb 2021 22:59:42

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-02-09T17:59:40', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'ada0e8de-bfb3-44e9-a718-c6570e935944' User entered '09 Feb 2021 17:59:40'	System	09 Feb 2021 22:59:42
	System	09 Feb 2021 22:59:42

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-02-15T17:18:49', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '9818f75e-80e3-4f29-895d-b613ae7ac667'	System	15 Feb 2021 22:18:56
User entered 'No (N)'	System	15 Feb 2021 22:18:56

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Have you been exposed to someone with 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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-02-15T17:18:50', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '9818f75e-80e3-4f29-895d-b613ae7ac667'	System	15 Feb 2021 22:18:56
User entered 'No (N)'	System	15 Feb 2021 22:18:56

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-02-15T17:18:53', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '9818f75e-80e3-4f29-895d-b613ae7ac667' User entered '15 Feb 2021 17:18:53'	System	15 Feb 2021 22:18:56
	System	15 Feb 2021 22:18:56

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-02-24T12:00:31-05:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '6c780604-c4a7-4077-90a6-f8a51986dc99'	System	24 Feb 2021 17:01:57
User entered 'No (N)'	System	24 Feb 2021 17:01:57

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

Have you been exposed to someone with 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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-02-24T12:00:32-05:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '6c780604-c4a7-4077-90a6-f8a51986dc99'	System	24 Feb 2021 17:01:57
User entered 'No (N)'	System	24 Feb 2021 17:01:57

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-02-24T12:00:35-05:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '6c780604-c4a7-4077-90a6-f8a51986dc99'	System	24 Feb 2021 17:01:57
User entered '24 Feb 2021 17:00:35'	System	24 Feb 2021 17:01:57

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-03-02T17:59:15-05:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'cde85c89-8258-4ce5-aa57-a39865b2a76e' User entered 'No (N)'	System	02 Mar 2021 22:59:23
	System	02 Mar 2021 22:59:23

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

Have you been exposed to someone with 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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-03-02T17:59:17-05:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'cde85c89-8258-4ce5-aa57-a39865b2a76e'	System	02 Mar 2021 22:59:23
User entered 'No (N)'	System	02 Mar 2021 22:59:23

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-03-02T17:59:19-05:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'cde85c89-8258-4ce5-aa57-a39865b2a76e' User entered '02 Mar 2021 17:59:19'	System	02 Mar 2021 22:59:23
	System	02 Mar 2021 22:59:23

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-03-08T12:00:35-05:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '040d2495-37af-4507-bc12-59ca78a3a184'	System	08 Mar 2021 17:01:12
User entered 'No (N)'	System	08 Mar 2021 17:01:12

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

Have you been exposed to someone with 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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-03-08T12:00:37-05:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '040d2495-37af-4507-bc12-59ca78a3a184'	System	08 Mar 2021 17:01:12
User entered 'No (N)'	System	08 Mar 2021 17:01:12

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-03-08T12:00:39-05:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '040d2495-37af-4507-bc12-59ca78a3a184' User entered '08 Mar 2021 12:00:39'	System	08 Mar 2021 17:01:12
	System	08 Mar 2021 17:01:12

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-03-15T15:04:19-04:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '5986838b-406f-4a68-a792-4f00584cb691'	System	15 Mar 2021 19:04:43
User entered 'No (N)'	System	15 Mar 2021 19:04:43

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Have you been exposed to someone with 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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-03-15T15:04:21-04:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '5986838b-406f-4a68-a792-4f00584cb691'	System	15 Mar 2021 19:04:43
User entered 'No (N)'	System	15 Mar 2021 19:04:43

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-03-15T15:04:24-04:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '5986838b-406f-4a68-a792-4f00584cb691' User entered '15 Mar 2021 15:04:24'	System	15 Mar 2021 19:04:43
	System	15 Mar 2021 19:04:43

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-03-22T12:00:21-04:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'd1940cad-cdb6-4d63-a1bb-e483c6ce50e6' User entered 'No (N)'	System	22 Mar 2021 16:00:51
	System	22 Mar 2021 16:00:51

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Have you been exposed to someone with 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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-03-22T12:00:22-04:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'd1940cad-cdb6-4d63-a1bb-e483c6ce50e6' User entered 'No (N)'	System	22 Mar 2021 16:00:51
	System	22 Mar 2021 16:00:51

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-03-22T12:00:25-04:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'd1940cad-cdb6-4d63-a1bb-e483c6ce50e6' User entered '22 Mar 2021 12:00:25'	System	22 Mar 2021 16:00:51
	System	22 Mar 2021 16:00:51

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-03-30T13:20:25-04:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'd1cd3345-1ba0-4454-b5ef-ade6163b41fe'	System	30 Mar 2021 17:20:37
User entered 'No (N)'	System	30 Mar 2021 17:20:37

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

Have you been exposed to someone with 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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-03-30T13:20:28-04:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'd1cd3345-1ba0-4454-b5ef-ade6163b41fe'	System	30 Mar 2021 17:20:37
User entered 'No (N)'	System	30 Mar 2021 17:20:37

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-03-30T13:20:31-04:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'd1cd3345-1ba0-4454-b5ef-ade6163b41fe' User entered '30 Mar 2021 13:20:31'	System	30 Mar 2021 17:20:37
	System	30 Mar 2021 17:20:37

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-04-06T17:59:23-04:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '9146bd82-ccea-4d5f-a803-93f2a45841da' User entered 'No (N)'	System	06 Apr 2021 21:59:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

Have you been exposed to someone with 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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-04-06T17:59:25-04:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '9146bd82-ccea-4d5f-a803-93f2a45841da' User entered 'No (N)'	System	06 Apr 2021 21:59:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-04-06T17:59:27-04:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '9146bd82-ccea-4d5f-a803-93f2a45841da' User entered '06 Apr 2021 17:59:27'	System	06 Apr 2021 21:59:31
	System	06 Apr 2021 21:59:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-04-12T11:37:14-04:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '21041aa0-c90f-405f-83b2-6e19579f8f58'	System	12 Apr 2021 15:37:21
User entered 'No (N)'	System	12 Apr 2021 15:37:21

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

Have you been exposed to someone with 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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-04-12T11:37:16-04:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '21041aa0-c90f-405f-83b2-6e19579f8f58'	System	12 Apr 2021 15:37:21
User entered 'No (N)'	System	12 Apr 2021 15:37:21

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-04-12T11:37:18-04:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '21041aa0-c90f-405f-83b2-6e19579f8f58'	System	12 Apr 2021 15:37:21
User entered '12 Apr 2021 11:37:18'	System	12 Apr 2021 15:37:21

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-04-20T17:59:23-04:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'a1a41ee1-e1bb-47f6-a723-ffc2ec8061e2' User entered 'No (N)'	System	20 Apr 2021 21:59:30
	System	20 Apr 2021 21:59:30

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Have you been exposed to someone with 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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-04-20T17:59:24-04:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'a1a41ee1-e1bb-47f6-a723-ffc2ec8061e2' User entered 'No (N)'	System	20 Apr 2021 21:59:30
	System	20 Apr 2021 21:59:30

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-04-20T17:59:26-04:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: 'a1a41ee1-e1bb-47f6-a723-ffc2ec8061e2'	System	20 Apr 2021 21:59:30
User entered '20 Apr 2021 17:59:26'	System	20 Apr 2021 21:59:30

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-04-26T12:00:28-04:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '7c0f6eb0-15a6-4970-9da5-bb34ae41c193'	System	26 Apr 2021 16:01:13
User entered 'No (N)'	System	26 Apr 2021 16:01:13

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Have you been exposed to someone with 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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-04-26T12:00:29-04:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '7c0f6eb0-15a6-4970-9da5-bb34ae41c193'	System	26 Apr 2021 16:01:13
User entered 'No (N)'	System	26 Apr 2021 16:01:13

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-04-26T12:00:31-04:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '7c0f6eb0-15a6-4970-9da5-bb34ae41c193'	System	26 Apr 2021 16:01:13
User entered '26 Apr 2021 12:00:31'	System	26 Apr 2021 16:01:13

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-05-02T12:42:47-04:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '73e79b7c-8018-4d35-90f0-61a011696412'	System	02 May 2021 16:46:45
User entered 'Yes (Y)'	System	02 May 2021 16:46:45

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Have you been exposed to someone with 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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-05-02T12:42:57-04:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '73e79b7c-8018-4d35-90f0-61a011696412'	System	02 May 2021 16:46:45
User entered 'No (N)'	System	02 May 2021 16:46:45

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-05-02T12:43:03-04:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '73e79b7c-8018-4d35-90f0-61a011696412'	System	02 May 2021 16:46:45
User entered 'No (N)'	System	02 May 2021 16:46:45

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[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 (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-05-02T12:46:39-04:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '73e79b7c-8018-4d35-90f0-61a011696412'	System	02 May 2021 16:46:45
User entered 'No (N)'	System	02 May 2021 16:46:45

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-05-02T12:46:42-04:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '73e79b7c-8018-4d35-90f0-61a011696412'	System	02 May 2021 16:46:45
User entered '02 May 2021 12:46:42'	System	02 May 2021 16:46:45

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '19 Nov 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '23 Nov 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '26 Nov 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '30 Nov 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '03 Dec 2022 00:01'	System	20 Nov 2020 11:25:31

US3432580

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Aug 2021 22:42:38

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 11:25:31
Amendment Manager: User entered '07 Dec 2022 23:59'	System	20 Nov 2020 11:25:31

US3432580

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:42:38

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 06:13:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-03-02T17:59:24-05:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '2c5e7d0e-87b9-4b00-b00a-c71186042160' User entered 'No (N)'	System	02 Mar 2021 22:59:30
	System	02 Mar 2021 22:59:30

US3432580

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 11 Aug 2021 22:42:38

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:13:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6CC737E7-8E62-45D3-8D63-F10C9747F6F7)', Time: '2021-03-02T17:59:28-05:00', User OID: 'PatientReportedOutcome (US3432580)', ODM File OID: '2c5e7d0e-87b9-4b00-b00a-c71186042160' User entered '02 Mar 2021 17:59:28'	System	02 Mar 2021 22:59:30
	System	02 Mar 2021 22:59:30

US3432580

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:25:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Dec 2020 14:59:04

US3432580

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:25:13
User entered '29 Dec 2020'	(b) (4), (b) (6)	29 Dec 2020 14:59:04

US3432580

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:25:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	29 Dec 2020 14:59:04

US3432580

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:25:13
User entered empty.	(b) (4), (b) (6)	29 Dec 2020 14:59:04

US3432580

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:42:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:25:05
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 16:25:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Dec 2020 14:59:10

US3432580

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:42:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 03:31:20
User entered 'I'	System	29 Dec 2020 14:59:10

US3432580

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:46:48
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:43:00
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
User entered 'Yes (Y)'	Bethany Evans (b) (4)	01 Feb 2021 19:19:46

US3432580

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:46:48
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:43:00
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
User entered '01 Feb 2021'	Bethany Evans (b) (4)	01 Feb 2021 19:19:46

US3432580

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:46:48
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:43:00
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
User entered 'Contact Made (CONTACT MADE)'	Bethany Evans (b) (4)	01 Feb 2021 19:19:46

US3432580

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:46:48
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:43:00
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
User entered empty.	Bethany Evans (b) (4)	01 Feb 2021 19:19:46

US3432580

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:42:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:46:48
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 03:44:01
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
User entered 'Yes (Y)'	Bethany Evans (b) (4)	01 Feb 2021 19:19:51

US3432580

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:42:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:46:48
User entered 'I'	System	01 Feb 2021 19:19:51

US3432580

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:46:48
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:43:33
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:20:44
User entered 'Yes (Y)'	Jessica Cauley (b) (4)	31 Mar 2021 21:00:22

US3432580

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:46:48
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:43:33
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:20:44
User entered '2 Mar 2021'	Jessica Cauley (b) (4)	31 Mar 2021 21:00:22

US3432580

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:46:48
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:43:33
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:20:44
User entered 'Contact Made (CONTACT MADE)'	Jessica Cauley (b) (4)	31 Mar 2021 21:00:22

US3432580

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:46:48
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:43:33
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:20:44
User entered empty.	Jessica Cauley (b) (4)	31 Mar 2021 21:00:22

US3432580

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:42:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:46:48
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:43:39
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:20:44
User entered 'Yes (Y)'	Jessica Cauley (b) (4)	31 Mar 2021 21:00:28

US3432580

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:42:38

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 21:46:48
User entered 'I'	System	31 Mar 2021 21:00:28

US3432580

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:44:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:20:44
User entered 'Yes (Y)'	Tenaizus Woods (b) (4)	01 Apr 2021 16:30:07

US3432580

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:44:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:20:44
User entered '1 Apr 2021'	Tenaizus Woods (b) (4)	01 Apr 2021 16:30:07

US3432580

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:44:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:20:44
User entered 'Contact Made (CONTACT MADE)'	Tenaizus Woods (b) (4)	01 Apr 2021 16:30:07

US3432580

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Aug 2021 22:42:38

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:44:08
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:20:44
User entered empty.	Tenaizus Woods (b) (4)	01 Apr 2021 16:30:07

US3432580

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:42:38

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 14:44:12
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:20:44
User entered 'Yes (Y)'	Tenaizus Woods (b) (4)	01 Apr 2021 16:30:10

US3432580

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Aug 2021 22:42:38

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Apr 2021 16:30:10

US3432580

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

Form: Visit Date

Generated On: 11 Aug 2021 22:42:38

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:18:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
User entered 'Yes (Y)'	Jessica Cauley (b) (4)	19 Jan 2021 19:27:15

US3432580

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

Form: Visit Date

Generated On: 11 Aug 2021 22:42:38

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:18:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
User entered '19 Jan 2021'	Jessica Cauley (b) (4)	19 Jan 2021 19:27:15

US3432580

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

Form: Visit Date

Generated On: 11 Aug 2021 22:42:38

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:18:03
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
User entered 'Clinic (Clinic)'	Jessica Cauley (b) (4)	19 Jan 2021 19:27:15

US3432580

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

Form: Visit Date

Generated On: 11 Aug 2021 22:42:38

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered 'UNBLND_DECIDE'	System	19 Jan 2021 19:27:15

US3432580

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

Form: Unblinding

Generated On: 11 Aug 2021 22:42:38

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:18:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
User entered '19 Jan 2021'	Jessica Cauley (b) (4)	19 Jan 2021 19:28:02

US3432580

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

Form: Unblinding

Generated On: 11 Aug 2021 22:42:38

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:27:57
DataPoint Verified.	(b) (4), (b) (6)	11 Apr 2021 06:13:08
User entered '0'	Julia Klopfer (b) (4)	09 Apr 2021 12:41:37
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 09:37:16

US3432580

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

Form: Unblinding

Generated On: 11 Aug 2021 22:42:38

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:18:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
User entered 'Yes (Y)'	Jessica Cauley (b) (4)	19 Jan 2021 19:28:02

US3432580

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

Form: Unblinding

Generated On: 11 Aug 2021 22:42:38

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:27:57
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 08:25:34
	(b) (4), (b) (6)	11 Apr 2021 06:13:08
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'y' (Site from DM).	Julia Klopfer (b) (4)	09 Apr 2021 12:41:40
User entered 'Amendment 6 or later (Amendment 6 or later)'	Julia Klopfer (b) (4)	09 Apr 2021 12:41:37
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 11:46:36
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:37:16

US3432580

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

Form: Unblinding

Generated On: 11 Aug 2021 22:42:38

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:18:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
User entered '19 Jan 2021'	Jessica Cauley (b) (4)	19 Jan 2021 19:28:02

US3432580

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

Form: Unblinding

Generated On: 11 Aug 2021 22:42:38

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:18:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
User entered 'mRNA-1273 (mRNA-1273)'	Jessica Cauley (b) (4)	19 Jan 2021 19:28:02

US3432580

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

Form: Unblinding

Generated On: 11 Aug 2021 22:42:38

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:18:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 05:06:59
User entered 'mRNA-1273 (mRNA-1273)'	Jessica Cauley (b) (4)	19 Jan 2021 19:28:02

US3432580

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

Form: Unblinding

Generated On: 11 Aug 2021 22:42:38

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:18:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 05:06:59
User entered 'mRNA-1273 (mRNA-1273)'	Jessica Cauley (b) (4)	19 Jan 2021 19:28:02

US3432580

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

Form: Unblinding

Generated On: 11 Aug 2021 22:42:38

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:18:11
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
User entered 'No (N)'	Jessica Cauley (b) (4)	19 Jan 2021 19:28:02

US3432580

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

Form: Unblinding

Generated On: 11 Aug 2021 22:42:38

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered empty.	System	19 Jan 2021 19:28:02

US3432580

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

Form: Unblinding

Generated On: 11 Aug 2021 22:42:38

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered empty.	System	19 Jan 2021 19:28:02

US3432580

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:42:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:20:07
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
User entered 'Yes (Y)'	Jessica Cauley (b) (4)	19 Jan 2021 21:41:18

US3432580

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:42:38

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:20:07
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
User entered '19 Jan 2021'	Jessica Cauley (b) (4)	19 Jan 2021 21:41:18

US3432580

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:42:38

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:20:07
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
User entered '14:25'	Jessica Cauley (b) (4)	19 Jan 2021 21:41:18

US3432580

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

Form: Immunogenicity Assessment

Generated On: 11 Aug 2021 22:42:38

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered '19 Jan 2021 14:25'	System	19 Jan 2021 21:41:18

US3432580

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:42:38

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:20:12
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
User entered 'Yes (Y)'	Jessica Cauley (b) (4)	19 Jan 2021 21:41:28

US3432580

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:20:12
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
User entered '19 Jan 2021'	Jessica Cauley (b) (4)	19 Jan 2021 21:41:28

US3432580

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:42:38

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 18:20:12
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
User entered '14:30'	Jessica Cauley (b) (4)	19 Jan 2021 21:41:28

US3432580

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Aug 2021 22:42:38

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 15:10:10
User entered '19 Jan 2021 14:30'	System	19 Jan 2021 21:41:28

US3432580

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 11 Aug 2021 22:42:38

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 03:48:32
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:20:44
User entered 'No (N)'	Tenaizus Woods (b) (4)	27 Feb 2021 13:24:14

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:24:04
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
User closed query 'Please add missing page of con-meds to EDC. flu vxn, biotin/keratin, multivitamin, biotin, and Zyrtec Cetirizine. ' (Site from CRA).	(b) (4), (b) (6)	06 Jan 2021 19:27:25
Query 'Please add missing page of con-meds to EDC. Alexander Mills flu vxn, biotin/keratin, multivitamin, biotin, and Zyrtec Cetirizine. ' answered with 'Updated' (Site from CRA).	(b) (4)	06 Jan 2021 15:27:09
User opened query 'Please add missing page of con-meds to EDC. flu vxn, biotin/keratin, multivitamin, biotin, and Zyrtec Cetirizine. ' (Site from CRA).	(b) (4), (b) (6)	16 Dec 2020 21:31:26
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:23:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 20:43:20

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:42:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 20:46:54
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 20:46:54
	(b) (4)	
Data point term sent to Coder	System	01 Oct 2020 20:46:06
Data point term sent to Coder	System	01 Oct 2020 20:45:03
User entered 'Albuterol'	(b) (4), (b) (6)	01 Oct 2020 20:44:25

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:42:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 20:44:25

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:42:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'asthma'	(b) (4), (b) (6)	01 Oct 2020 20:44:25

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:42:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'I'	(b) (4), (b) (6)	01 Oct 2020 20:44:25

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:42:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User closed query 'Per CDM: Dose Unit is recorded as 'Other-PUFF', however PUFF is an option in the drop down menu. Please review and update Dose Unit as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 07:15:46
Query 'Per CDM: Dose Unit is recorded as 'Other-PUFF', however PUFF is an option in the drop down menu. Please review and update Dose Unit as appropriate.' answered with 'Updated' (Site from DM).	Alexander Mills (b) (4)	11 Nov 2020 21:36:21
User entered 'puff (PUFF)' reason for change: Data Entry Error	Alexander Mills (b) (4)	11 Nov 2020 21:36:14
User opened query 'Per CDM: Dose Unit is recorded as 'Other-PUFF', however PUFF is an option in the drop down menu. Please review and update Dose Unit as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 16:20:02
User entered 'Other (OTHER)'	(b) (4), (b) (6)	01 Oct 2020 20:44:25

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:42:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered empty; reason for change Data Entry Error	Alexander Mills (b) (4)	11 Nov 2020 21:36:14
	(b) (4)	
User entered 'puff'	(b) (4), (b) (6)	01 Oct 2020 20:44:25

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:42:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'as needed (PRN)'	(b) (4), (b) (6)	01 Oct 2020 20:44:25

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:42:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:44:25

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:42:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))' reason for change: New Information	(b) (4), (b) (6)	01 Oct 2020 20:45:14
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 20:44:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Oct 2020 20:44:49
User entered 'Oral (ORAL)' reason for change: New Information	(b) (4), (b) (6)	01 Oct 2020 20:44:49
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Oct 2020 20:44:25
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:44:25

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:42:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:44:25

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'un UNK 1980'	(b) (4), (b) (6)	01 Oct 2020 20:44:25

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:42:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 20:44:25

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:42:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 20:44:25

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:42:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:44:25

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:42:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 20:44:25

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:42:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 20:44:25

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:42:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 20:44:25

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Aug 2021 22:42:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 20:44:25

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:42:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
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.	Coder Import (b) (4) (b) (4)	01 Oct 2020 20:47:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 20:47:50
Data point term sent to Coder	System	01 Oct 2020 20:47:10
User entered 'Losartan'	(b) (4), (b) (6)	01 Oct 2020 20:46:43

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:42:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 20:46:43

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:42:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'HTN'	(b) (4), (b) (6)	01 Oct 2020 20:46:43

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:42:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered '50'	(b) (4), (b) (6)	01 Oct 2020 20:46:43

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:42:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Oct 2020 20:46:43

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:42:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:46:43

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:42:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'once daily (QD)'	(b) (4), (b) (6)	01 Oct 2020 20:46:43

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:42:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:46:43

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:42:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Oct 2020 20:46:43

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:42:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:46:43

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'un UNK 2008'	(b) (4), (b) (6)	01 Oct 2020 20:46:43

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:42:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 20:46:43

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:42:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 20:46:43

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:42:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:46:43

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:42:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 20:46:43

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:42:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 20:46:43

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:42:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 20:46:43

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Aug 2021 22:42:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 20:46:43

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:42:38

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 20:48:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 20:48:52
Data point term sent to Coder User entered 'Amlodipine'	System (b) (4), (b) (6)	01 Oct 2020 20:48:12 01 Oct 2020 20:47:31

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:42:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 20:47:31

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:42:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'HTN'	(b) (4), (b) (6)	01 Oct 2020 20:47:31

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:42:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered '10'	(b) (4), (b) (6)	01 Oct 2020 20:47:31

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:42:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Oct 2020 20:47:31

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:42:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:47:31

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:42:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'once daily (QD)'	(b) (4), (b) (6)	01 Oct 2020 20:47:31

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:42:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:47:31

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:42:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Oct 2020 20:47:31

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:42:38

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:47:31

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'un UNK 2008'	(b) (4), (b) (6)	01 Oct 2020 20:47:31

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:42:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 20:47:31

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:42:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 20:47:31

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:42:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:47:31

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:42:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 20:47:31

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:42:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 20:47:31

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:42:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 20:47:31

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Aug 2021 22:42:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 20:47:31

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:42:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION HYDROCHLORIDE, PRODUCTSYNONYM: WELLBUTRIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 20:49:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Oct 2020 20:49:54
Data point term sent to Coder	System	01 Oct 2020 20:49:14
User entered 'Wellbutin'	(b) (4), (b) (6)	01 Oct 2020 20:48:22

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:42:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 20:48:22

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:42:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'Depression'	(b) (4), (b) (6)	01 Oct 2020 20:48:22

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:42:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered '100'	(b) (4), (b) (6)	01 Oct 2020 20:48:22

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:42:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Oct 2020 20:48:22

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:42:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:48:22

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:42:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'once daily (QD)'	(b) (4), (b) (6)	01 Oct 2020 20:48:22

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:42:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:48:22

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:42:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Oct 2020 20:48:22

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:42:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:48:22

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'un UNK 2018'	(b) (4), (b) (6)	01 Oct 2020 20:48:22

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:42:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 20:48:22

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:42:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 20:48:22

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:42:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:48:22

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:42:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 20:48:22

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:42:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 20:48:22

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:42:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 20:48:22

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Aug 2021 22:42:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 20:48:22

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:42:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: TEMAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 20:50:58
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 20:50:58
	(b) (4)	
Data point term sent to Coder	System	01 Oct 2020 20:50:15
User entered 'temazepam'	(b) (4), (b) (6)	01 Oct 2020 20:49:24
	(b) (4), (b) (6)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:42:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 20:49:24

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:42:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'insomnia'	(b) (4), (b) (6)	01 Oct 2020 20:49:24

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:42:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered '30'	(b) (4), (b) (6)	01 Oct 2020 20:49:24

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:42:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Oct 2020 20:49:24

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:42:38

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:49:24

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:42:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'as needed (PRN)'	(b) (4), (b) (6)	01 Oct 2020 20:49:24

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:42:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:49:24

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:42:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Oct 2020 20:49:24

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:42:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:49:24

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'un UNK 2018'	(b) (4), (b) (6)	01 Oct 2020 20:49:24

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:42:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 20:49:24

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:42:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 20:49:24

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:42:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:49:24

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:42:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 20:49:24

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:42:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 20:49:24

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:42:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 20:49:24

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Aug 2021 22:42:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Oct 2020 20:49:24

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:42:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 20:52:00
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Oct 2020 20:52:00
	(b) (4)	
Data point term sent to Coder	System	01 Oct 2020 20:51:17
User entered 'omeprazole'	(b) (4), (b) (6)	01 Oct 2020 20:50:41

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:42:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 20:50:41

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:42:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'GERD'	(b) (4), (b) (6)	01 Oct 2020 20:50:41

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:42:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered '20'	(b) (4), (b) (6)	01 Oct 2020 20:50:41

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:42:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'mg (mg)'	(b) (4), (b) (6)	01 Oct 2020 20:50:41

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:42:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:50:41

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:42:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'once daily (QD)'	(b) (4), (b) (6)	01 Oct 2020 20:50:41

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:42:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:50:41

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:42:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	01 Oct 2020 20:50:41

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:42:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:50:41

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:42:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'un UNK 2019'	(b) (4), (b) (6)	01 Oct 2020 20:50:41

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:42:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered '0'	(b) (4), (b) (6)	01 Oct 2020 20:50:41

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:42:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 20:50:41

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:42:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:50:41

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:42:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'No (N)'	(b) (4), (b) (6)	01 Oct 2020 20:50:41

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:42:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 20:50:41

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:42:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 20:50:41

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Aug 2021 22:42:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Oct 2020 20:50:41

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:42:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, POTENT (GROUP III), PRODUCT: BETAMETHASONE DIPROPIONATE, PRODUCTSYNONYM: BETAMETHASONE DIPROPIONATE, AUGMENTED - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 15:12:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 15:12:38
Data point term sent to Coder	System	22 Oct 2020 14:07:45
User entered 'Betamethasone, Augmented 0.05 % Topical Cream'	(b) (4), (b) (6)	22 Oct 2020 14:07:04

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:42:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'No (N)'	(b) (4), (b) (6)	22 Oct 2020 14:07:04

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:42:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'eczema'	(b) (4), (b) (6)	22 Oct 2020 14:07:04

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:42:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Monica Feeley (b) (4)	27 Oct 2020 19:55:18
	(b) (4)	
User entered 'thin film'	(b) (4), (b) (6)	22 Oct 2020 14:07:04
	(b) (4), (b) (6)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:42:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'Other (OTHER)'	(b) (4), (b) (6)	22 Oct 2020 14:07:04

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:42:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'Application' reason for change: Data Entry Error	Monica Feeley (b) (4)	27 Oct 2020 19:55:18
User entered 'topical cream'	(b) (4), (b) (6)	22 Oct 2020 14:07:04

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:42:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'twice daily (BID)'	(b) (4), (b) (6)	22 Oct 2020 14:07:04

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:42:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 14:07:04

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:42:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'Topical (TOPICAL)'	(b) (4), (b) (6)	22 Oct 2020 14:07:04

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:42:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 14:07:04

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered '15 Oct 2020'	(b) (4), (b) (6)	22 Oct 2020 14:07:04

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:42:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered '0'	(b) (4), (b) (6)	22 Oct 2020 14:07:04

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:42:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Oct 2020 14:07:04

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:42:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 14:07:04

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:42:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 14:07:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 14:07:11
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Oct 2020 14:07:11
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 14:07:04
User entered empty.	(b) (4), (b) (6)	22 Oct 2020 14:07:04

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:42:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Oct 2020 14:07:04

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:42:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 14:07:04

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Aug 2021 22:42:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Oct 2020 14:07:04

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:42:38

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:14:33
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 14:39:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Nov 2020 14:39:47
Data point term sent to Coder	System	12 Nov 2020 14:38:55
User entered 'Tylenol'	(b) (4), (b) (6)	12 Nov 2020 14:38:26

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:42:38

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:14:33
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 14:38:26

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:42:38

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:14:33
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHES AND MUSCLE ACHES are considered solicited local or systemic adverse reactions, and meet any of the following criteria: result in a visit to a healthcare provider (MAAE), lead to withdrawal from the study or study vaccination, or otherwise meet the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reactions of HEADACHES AND MUSCLE ACHES did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 16:02:10
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHES AND MUSCLE ACHES are considered solicited local or systemic adverse reactions, and meet any of the following criteria: result in a visit to a healthcare provider (MAAE), lead to withdrawal from the study or study vaccination, or otherwise meet the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reactions of HEADACHES AND MUSCLE ACHES did not meet the AE reporting criteria. ' answered with 'see diary' (Site from DM).	Monica Feeley (b) (4)	27 Jan 2021 22:14:53

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:42:38

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHES AND MUSCLE ACHES are considered solicited local or systemic adverse reactions, and meet any of the following criteria: result in a visit to a healthcare provider (MAAE), lead to withdrawal from the study or study vaccination, or otherwise meet the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reactions of HEADACHES AND MUSCLE ACHES did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	26 Jan 2021 09:12:58
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'Headaches and Muscle Aches'	(b) (4), (b) (6)	12 Nov 2020 14:38:26

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:42:38

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:14:33
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered '1000'	(b) (4), (b) (6)	12 Nov 2020 14:38:26

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:42:38

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:14:33
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'mg (mg)'	(b) (4), (b) (6)	12 Nov 2020 14:38:26

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:42:38

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:14:33
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 14:38:26

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:42:38

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:14:33
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'twice daily (BID)'	(b) (4), (b) (6)	12 Nov 2020 14:38:26

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:42:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:14:33
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 14:38:26

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:42:38

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:14:33
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	12 Nov 2020 14:38:26

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:42:38

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:14:33
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 14:38:26

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:14:33
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered '6 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 14:38:26

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:42:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:14:33
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered '0'	(b) (4), (b) (6)	12 Nov 2020 14:38:26

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:42:38

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:14:33
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 14:38:26

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:42:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:14:33
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered '6 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 14:38:26

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:42:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:14:33
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	16 Dec 2020 21:26:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 14:38:26

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:42:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:14:33
User entered '2'	System	12 Nov 2020 14:38:26

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:42:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:14:33
User entered '1'	System	12 Nov 2020 14:38:26

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Aug 2021 22:42:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 15:14:33
User entered '804 (804)'	System	12 Nov 2020 14:38:26

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:42:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER VITAMIN PRODUCTS, COMBINATIONS, ATC: VITAMINS, OTHER COMBINATIONS, PRODUCT: BIOTIN;KERATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Jan 2021 15:25:41
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Jan 2021 15:25:41
	(b) (4)	
Data point term sent to Coder	System	06 Jan 2021 15:20:57
User entered 'Biotin + Keratin'	Alexander Mills (b) (4)	06 Jan 2021 15:20:08
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:42:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered 'No (N)'	Alexander Mills (b) (4)	06 Jan 2021 15:20:08
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:42:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
	(b) (4), (b) (6)	12 Feb 2021 10:48:53
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 and Update eCRF as appropriate. ' (Site from DM).	Monica Feeley (b) (4)	10 Feb 2021 21:49:57
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 and Update eCRF as appropriate. ' answered with 'no underlying medical condition. they want better hair growth. ' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 14:27:03
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 and Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 19:27:00
DataPoint Verified.	(b) (4)	06 Jan 2021 15:20:08
User entered 'Hair growth'	Alexander Mills (b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:42:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered '10,000/100'	Alexander Mills (b) (4)	06 Jan 2021 15:20:08
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:42:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered 'Other (OTHER)'	Alexander Mills (b) (4)	06 Jan 2021 15:20:08
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:42:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered 'ug/mg'	Alexander Mills (b) (4)	06 Jan 2021 15:20:08
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:42:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered 'once daily (QD)'	Alexander Mills (b) (4)	06 Jan 2021 15:20:08
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:42:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
	(b) (4), (b) (6)	06 Jan 2021 19:27:00
DataPoint Verified.	Alexander Mills (b) (4)	06 Jan 2021 15:20:08
User entered empty.	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:42:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered 'Oral (ORAL)'	Alexander Mills (b) (4)	06 Jan 2021 15:20:08
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:42:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered empty.	Alexander Mills (b) (4)	06 Jan 2021 15:20:08
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:42:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered '31 Oct 2020'	Alexander Mills (b) (4)	06 Jan 2021 15:20:08
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:42:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered '0'	Alexander Mills (b) (4)	06 Jan 2021 15:20:08
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:42:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered 'Yes (Y)'	Alexander Mills (b) (4)	06 Jan 2021 15:20:08
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:42:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered empty.	Alexander Mills (b) (4)	06 Jan 2021 15:20:08
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:42:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered 'No (N)'	Alexander Mills (b) (4)	06 Jan 2021 15:20:08
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:42:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 15:20:08

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:42:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 15:20:08

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Aug 2021 22:42:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Jan 2021 15:20:08

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:42:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
	(b) (4), (b) (6)	06 Jan 2021 19:27:00
DataPoint Verified.	Coder Import (b) (4)	06 Jan 2021 15:25:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER VITAMIN PRODUCTS, COMBINATIONS, ATC: COMBINATIONS OF VITAMINS, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Jan 2021 15:25:41
	(b) (4)	
Data point term sent to Coder	System	06 Jan 2021 15:22:57
User entered 'Multivitamin'	Alexander Mills (b) (4)	06 Jan 2021 15:22:40
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:42:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered 'Yes (Y)'	Alexander Mills (b) (4)	06 Jan 2021 15:22:40
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:42:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered 'General health (prophylaxis)'	Alexander Mills (b) (4)	06 Jan 2021 15:22:40
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:42:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered 'unk'	Alexander Mills (b) (4)	06 Jan 2021 15:22:40
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:42:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered 'Other (OTHER)'	Alexander Mills (b) (4)	06 Jan 2021 15:22:40
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:42:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered 'unknown'	Alexander Mills (b) (4)	06 Jan 2021 15:22:40
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:42:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered 'once daily (QD)'	Alexander Mills (b) (4)	06 Jan 2021 15:22:40
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:42:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered empty.	Alexander Mills (b) (4)	06 Jan 2021 15:22:40
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:42:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered 'Oral (ORAL)'	Alexander Mills (b) (4)	06 Jan 2021 15:22:40
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:42:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered empty.	Alexander Mills (b) (4)	06 Jan 2021 15:22:40
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:42:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered 'un UNK 2015'	Alexander Mills (b) (4)	06 Jan 2021 15:22:40
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:42:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered '0'	Alexander Mills (b) (4)	06 Jan 2021 15:22:40
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:42:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered 'Yes (Y)'	Alexander Mills (b) (4)	06 Jan 2021 15:22:40
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:42:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered empty.	Alexander Mills (b) (4)	06 Jan 2021 15:22:40
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:42:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered 'No (N)'	Alexander Mills (b) (4)	06 Jan 2021 15:22:40
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:42:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 15:22:40

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:42:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 15:22:40

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Aug 2021 22:42:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Jan 2021 15:22:40

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:42:38

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
	(b) (4), (b) (6)	06 Jan 2021 19:27:00
DataPoint Verified.	Coder Import (b) (4)	06 Jan 2021 15:25:41
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: BIOTIN - version WHODrug-Global-B3\\202003.	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Jan 2021 15:25:41
Data point term sent to Coder User entered 'Biotin'	System	06 Jan 2021 15:24:58
	Alexander Mills (b) (4)	06 Jan 2021 15:24:27
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:42:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered 'No (N)'	Alexander Mills (b) (4)	06 Jan 2021 15:24:27
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:42:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
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 and Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Feb 2021 10:49:01
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 and Update eCRF as appropriate. ' answered with 'no underlying medical condition. This person wants better hair growth.' (Site from DM).	Monica Feeley (b) (4)	10 Feb 2021 21:50:36
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 and Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 14:27:23
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered 'Hair growth'	Alexander Mills (b) (4)	06 Jan 2021 15:24:27
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:42:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered '1000'	Alexander Mills (b) (4)	06 Jan 2021 15:24:27
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:42:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered 'ug (ug)'	Alexander Mills (b) (4)	06 Jan 2021 15:24:27
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:42:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered empty.	Alexander Mills (b) (4)	06 Jan 2021 15:24:27
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:42:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered 'once daily (QD)'	Alexander Mills (b) (4)	06 Jan 2021 15:24:27
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:42:38

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered empty.	Alexander Mills (b) (4)	06 Jan 2021 15:24:27
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:42:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered 'Oral (ORAL)'	Alexander Mills (b) (4)	06 Jan 2021 15:24:27
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:42:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered empty.	Alexander Mills (b) (4)	06 Jan 2021 15:24:27
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:42:38

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered 'un UNK 2010'	Alexander Mills (b) (4)	06 Jan 2021 15:24:27
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:42:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered '0'	Alexander Mills (b) (4)	06 Jan 2021 15:24:27
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:42:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered 'Yes (Y)'	Alexander Mills (b) (4)	06 Jan 2021 15:24:27
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:42:38

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered empty.	Alexander Mills (b) (4)	06 Jan 2021 15:24:27
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:42:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered 'No (N)'	Alexander Mills (b) (4)	06 Jan 2021 15:24:27
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:42:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 15:24:27

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:42:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 15:24:27

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Aug 2021 22:42:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Jan 2021 15:24:27

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:42:38

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
	(b) (4), (b) (6)	06 Jan 2021 19:27:00
DataPoint Verified.	Coder Import (b) (4)	06 Jan 2021 15:34:41
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Jan 2021 15:34:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	System	06 Jan 2021 15:27:01
Data point term sent to Coder	Alexander Mills (b) (4)	06 Jan 2021 15:26:38
User entered 'Zyterc Cetrizine'	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:42:38

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered 'No (N)'	Alexander Mills (b) (4)	06 Jan 2021 15:26:38
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:42:38

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
	(b) (4), (b) (6)	06 Jan 2021 19:27:00
DataPoint Verified.	Alexander Mills (b) (4)	06 Jan 2021 15:26:38
User entered 'Environmental allergies'	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:42:38

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered '10'	Alexander Mills (b) (4)	06 Jan 2021 15:26:38
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:42:38

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered 'mg (mg)'	Alexander Mills (b) (4)	06 Jan 2021 15:26:38
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:42:38

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered empty.	Alexander Mills (b) (4)	06 Jan 2021 15:26:38
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:42:38

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered 'once daily (QD)'	Alexander Mills (b) (4)	06 Jan 2021 15:26:38
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:42:38

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered empty.	Alexander Mills (b) (4)	06 Jan 2021 15:26:38
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:42:38

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered 'Oral (ORAL)'	Alexander Mills (b) (4)	06 Jan 2021 15:26:38
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:42:38

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered empty.	Alexander Mills (b) (4)	06 Jan 2021 15:26:38
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:42:38

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered 'un UNK 2006'	Alexander Mills (b) (4)	06 Jan 2021 15:26:38
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:42:38

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered '0'	Alexander Mills (b) (4)	06 Jan 2021 15:26:38
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:42:38

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered 'Yes (Y)'	Alexander Mills (b) (4)	06 Jan 2021 15:26:38
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:42:38

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 19:27:00
User entered empty.	Alexander Mills (b) (4)	06 Jan 2021 15:26:38
	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:42:38

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:24:48
	(b) (4), (b) (6)	06 Jan 2021 19:27:00
DataPoint Verified.	Alexander Mills (b) (4)	06 Jan 2021 15:26:38
User entered 'No (N)'	(b) (4)	

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:42:38

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 15:26:38

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:42:38

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Jan 2021 15:26:38

US3432580

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Aug 2021 22:42:38

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Jan 2021 15:26:38

US3432580

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Aug 2021 22:42:38

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:20:44
	(b) (4), (b) (6)	03 Mar 2021 18:20:43
DataPoint Verified.	Tenaizus Woods (b) (4)	27 Feb 2021 13:22:34
User entered 'No (N)'	(b) (4)	