

US3432229 (Prod: Brigham and Womens Hospital)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:35:54

All time stamps listed in this document are displayed in GMT

US3432229

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 02:05:26

Generated On: 09 Jun 2021 17:35:54

Participant ID

US3432229

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

US3432229

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 02:05:49

Generated On: 09 Jun 2021 17:35:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3432229

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 02:05:48

Generated On: 09 Jun 2021 17:35:54

Date of Birth (MMM yyyy)	(b) (6) 1996
Age	24
Age Units	YEARS
Age (Derived)	24
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 02:05:48

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Date of Informed Consent (<i>dd MMM yyyy</i>)	21 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input checked="" type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 02:05:49

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 19 Feb 2021 02:05:49

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 19 Feb 2021 02:05:49

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Condition	ADHD
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 19 Feb 2021 02:05:49

Generated On: 09 Jun 2021 17:35:54

Condition	MOOD DISORDER
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Start Year (derived)	2009
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 19 Feb 2021 02:05:49

Generated On: 09 Jun 2021 17:35:54

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Start Year (derived)	1998
Stop Month and Year (derived)	
Stop Year (derived)	

US3432229

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 19 Feb 2021 02:05:49

Generated On: 09 Jun 2021 17:35:54

Condition	ORTHOSTATIC PRE-SYNCOPIY
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Start Year (derived)	2009
Stop Month and Year (derived)	
Stop Year (derived)	

US3432229

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 19 Feb 2021 02:05:49

Generated On: 09 Jun 2021 17:35:54

Condition	DYSMENORRHEA
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

US3432229

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 02:05:49

Generated On: 09 Jun 2021 17:35:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 AUG 2020
Time of assessment (00:00-23:59)	10:32 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 10:32
Height (xxx.x)	159.1 cm
Weight (xxx.x)	067.2 kg
BMI (xxx.x)	26.54782 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 02:05:49

Generated On: 09 Jun 2021 17:35:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 19 Feb 2021 02:05:48

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Date of assessment (dd MMM yyyy) 21 AUG 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

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

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 02:05:49

Generated On: 09 Jun 2021 17:35:54

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	21 AUG 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 02:05:49

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 02:05:49

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	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	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 02:05:49

Generated On: 09 Jun 2021 17:35:54

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

Visit date (dd MMM yyyy)	21 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 02:05:49

Generated On: 09 Jun 2021 17:35:54

What was the date of randomization? (dd MMM yyyy) 21 AUG 2020

What was the participant's randomization number? 144547

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

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

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

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

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

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

Liver Disease Yes ☐
 No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐
 No ☐

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 02:05:49

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 02:05:49

Generated On: 09 Jun 2021 17:35:54

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)	21 AUG 2020
Time of assessment (00:00-23:59)	10:32 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 10:32
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	077 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	10 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	069 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 02:05:49

Generated On: 09 Jun 2021 17:35:54

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)	21 AUG 2020
Time of assessment (00:00-23:59)	13:26 (24 HR)
Vital Signs Date and Time (derived)	21 AUG 2020 13:26
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)	073 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	075 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 02:05:49

Generated On: 09 Jun 2021 17:35:54

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 02:05:49

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Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 02:05:49

Generated On: 09 Jun 2021 17:35:54

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) 21 AUG 2020

What was the treatment time? (00:00-23:59) 12:56 (24 HR)

Treatment Date and Time (derived) 21 AUG 2020 12:56

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 02:05:49

Generated On: 09 Jun 2021 17:35:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 AUG 2020
Collection time (00:00-23:59)	11:00 (24 HR)
Collection date and time (derived)	21 AUG 2020 11:00

US3432229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 02:05:49

Generated On: 09 Jun 2021 17:35:54

Collection date (dd MMM yyyy)			21 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:05	21 AUG 2020 11:05
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:05:49

Generated On: 09 Jun 2021 17:35:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.8 °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 21 AUG 2020 13:31

PC Open Date & Time 21 AUG 2020 13:16

PC Close Date & Time 21 AUG 2020 15:46

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐
No ☒

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

PC Time Stamp	21 AUG 2020 16:50
PC Open Date & Time	21 AUG 2020 16:41
PC Close Date & Time	22 AUG 2020 11:59

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:54

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	22 AUG 2020 18:40
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.3 °F

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

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

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

To **PREVENT** pain or fever from occurring True

PC Time Stamp 24 AUG 2020 10:48

PC Open Date & Time 23 AUG 2020 12:00

PC Close Date & Time 24 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 22:40

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 22:43

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:54

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	27 AUG 2020 07:55
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 23:59

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

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 ☐

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

53

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

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

Yes ☒

No ☐

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

5

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 13:34

PC Open Date & Time

21 AUG 2020 13:16

PC Close Date & Time

21 AUG 2020 15:46

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

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

21 AUG 2020 16:52

PC Open Date & Time

21 AUG 2020 16:41

PC Close Date & Time

22 AUG 2020 11:59

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:54

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

22 AUG 2020 18:40

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:54

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

24 AUG 2020 10:48

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:54

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

24 AUG 2020 22:38

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:54

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

25 AUG 2020 22:43

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:54

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

27 AUG 2020 07:55

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:54

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

27 AUG 2020 23:59

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

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 ☐

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 13:34
PC Open Date & Time	21 AUG 2020 13:16
PC Close Date & Time	21 AUG 2020 15:46

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

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 ☐

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

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

No ☒

Yes ☐

PC Time stamp	21 AUG 2020 16:51
PC Open Date & Time	21 AUG 2020 16:41
PC Close Date & Time	22 AUG 2020 11:59

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:54

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 ☒

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:54

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 18:41
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:54

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 10:49
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:54

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

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EAB) (1725)

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:54

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 22:38
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

55 of 2239

EAB) (1725)

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:54

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 22:44
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:54

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 ☒

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:54

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 07:56
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:54

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

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EAB) (1725)

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:54

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

US3432229

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:05:48

Generated On: 09 Jun 2021 17:35:54

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3432229

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:05:48

Generated On: 09 Jun 2021 17:35:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432229

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:05:27

Generated On: 09 Jun 2021 17:35:54

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 05 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3432229

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:05:27

Generated On: 09 Jun 2021 17:35:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432229

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:05:27

Generated On: 09 Jun 2021 17:35:54

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3432229

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:05:27

Generated On: 09 Jun 2021 17:35:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432229

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 02:05:50

Generated On: 09 Jun 2021 17:35:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3432229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 02:05:50

Generated On: 09 Jun 2021 17:35:54

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)	18 SEP 2020
Time of assessment (00:00-23:59)	10:47 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 10:47
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3432229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 02:05:50

Generated On: 09 Jun 2021 17:35:54

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)	18 SEP 2020
Time of assessment (00:00-23:59)	11:44 (24 HR)
Vital Signs Date and Time (derived)	18 SEP 2020 11:44
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	IR
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	61 mmHg
Diastolic Blood Pressure units	MMHG

US3432229

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 02:05:50

Generated On: 09 Jun 2021 17:35:54

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 SEP 2020

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

US3432229

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 19 Feb 2021 02:05:50

Generated On: 09 Jun 2021 17:35:54

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	18 SEP 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)	

US3432229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 02:05:50

Generated On: 09 Jun 2021 17:35:54

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) 18 SEP 2020

What was the treatment time? (00:00-23:59) 11:14 (24 HR)

Treatment Date and Time (derived) 18 SEP 2020 11:14

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

US3432229

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 02:05:50

Generated On: 09 Jun 2021 17:35:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 SEP 2020
Collection time (00:00-23:59)	11:00 (24 HR)
Collection date and time (derived)	18 SEP 2020 11:00

US3432229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 02:05:50

Generated On: 09 Jun 2021 17:35:54

Collection date (dd MMM yyyy)			18 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:05	18 SEP 2020 11:05
Nasopharyngeal Swab 2	No		

US3432229

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:05:50

Generated On: 09 Jun 2021 17:35:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

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

18 SEP 2020 11:45

PC Open Date & Time

18 SEP 2020 11:34

PC Close Date & Time

18 SEP 2020 14:04

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐
No ☒

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

PC Time Stamp	18 SEP 2020 20:50
PC Open Date & Time	18 SEP 2020 14:59
PC Close Date & Time	19 SEP 2020 11:59

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:54

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	99.3 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	19 SEP 2020 12:54
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.0 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	20 SEP 2020 17:07
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:54

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 00:00

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 02:55

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:54

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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

23 SEP 2020 21:41

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 23:59

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

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

18 SEP 2020 11:46

PC Open Date & Time

18 SEP 2020 11:34

PC Close Date & Time

18 SEP 2020 14:04

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

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

18 SEP 2020 20:50

PC Open Date & Time

18 SEP 2020 14:59

PC Close Date & Time

19 SEP 2020 11:59

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:54

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

19 SEP 2020 12:54

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:54

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

20 SEP 2020 17:03

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:54

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

22 SEP 2020 00:00

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:54

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

23 SEP 2020 02:55

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:54

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

23 SEP 2020 21:41

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:54

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

24 SEP 2020 23:59

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

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 ☐

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

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

No ☒

Yes ☐

PC Time stamp	18 SEP 2020 11:46
PC Open Date & Time	18 SEP 2020 11:34
PC Close Date & Time	18 SEP 2020 14:04

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

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 ☐

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

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

No ☒

Yes ☐

PC Time stamp	18 SEP 2020 20:51
PC Open Date & Time	18 SEP 2020 14:59
PC Close Date & Time	19 SEP 2020 11:59

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:54

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 ☐

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:54

	Yes <input type="checkbox"/>
PC Time stamp	19 SEP 2020 12:55
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:54

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 ☒

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:54

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 17:03
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:54

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 ☐

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:54

	Yes <input type="checkbox"/>
PC Time stamp	22 SEP 2020 00:01
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:54

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 02:56
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:54

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 ☐

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:54

	Yes <input type="radio"/>
PC Time stamp	23 SEP 2020 21:42
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:54

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

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EAB) (1725)

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:54

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 23:59
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 8

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 ☐

PC Time Stamp 26 SEP 2020 00:00

PC Open Date & Time 25 SEP 2020 12:00

PC Close Date & Time 26 SEP 2020 11:59

US3432229

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="radio"/> Yes <input checked="" type="radio"/>
PC Time stamp	26 SEP 2020 00:00
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3432229

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:05:27

Generated On: 09 Jun 2021 17:35:54

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3432229

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:05:27

Generated On: 09 Jun 2021 17:35:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432229

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:05:27

Generated On: 09 Jun 2021 17:35:54

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3432229

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:05:27

Generated On: 09 Jun 2021 17:35:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432229

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:05:48

Generated On: 09 Jun 2021 17:35:54

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3432229

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:05:27

Generated On: 09 Jun 2021 17:35:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432229

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 02:05:50

Generated On: 09 Jun 2021 17:35:54

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	VISIT3

US3432229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 02:05:50

Generated On: 09 Jun 2021 17:35:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 OCT 2020
Time of assessment (00:00-23:59)	11:24 (24 HR)
Vital Signs Date and Time (derived)	16 OCT 2020 11:24
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	104 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	58 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432229

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 02:05:50

Generated On: 09 Jun 2021 17:35:54

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.

US3432229

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 02:05:50

Generated On: 09 Jun 2021 17:35:54

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 16 OCT 2020

Collection time (00:00-23:59) 11:39 (24 HR)

Collection date and time (derived) 16 OCT 2020 11:39

US3432229

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:05:50

Generated On: 09 Jun 2021 17:35:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 OCT 2020 12:00:26

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	31 OCT 2020 18:45:23
Patient Cloud Open Date & Time	28 OCT 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
122 of 2239	

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

01 NOV 2020 23:59

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 NOV 2020 11:59:17

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

26 NOV 2020 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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 <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"/>

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

03 DEC 2020 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

06 DEC 2020 11:59:34

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

15 DEC 2020 18:45:48

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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 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	22 DEC 2020 12:00:39
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 DEC 2020 10:54:37
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	True
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	06 JAN 2021 17:59:51
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

13 JAN 2021 16:47:53

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 JAN 2021 18:05:11

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

27 JAN 2021 18:35:18

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 FEB 2021 12:18:09

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT	DAY 173
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	09 FEB 2021 12:27:11
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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	17 FEB 2021 10:23:25
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

25 FEB 2021 19:17:11

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 MAR 2021 12:26:16
Patient Cloud Open Date & Time	28 FEB 2021 00:01
Patient Cloud Close Date & Time	04 MAR 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 MAR 2021 14:43:04
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 208

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 MAR 2021 20:02:07
Patient Cloud Open Date & Time	21 MAR 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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 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	31 MAR 2021 17:59:22
Patient Cloud Open Date & Time	28 MAR 2021 00:01
Patient Cloud Close Date & Time	01 APR 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 229

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

04 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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"/>

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 APR 2021 00:01
Patient Cloud Close Date & Time	15 APR 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 17:59:30

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 250

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

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

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

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

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

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

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 ☐

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 APR 2021 00:01
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Patient Cloud Close Date & Time	29 APR 2021 23:59
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US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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 ☐

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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"/>

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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"/>

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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"/>

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 JUN 2021 00:01
Patient Cloud Close Date & Time	10 JUN 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

Date and time of submission	
Patient Cloud Open Date & Time	13 JUN 2021 00:01
Patient Cloud Close Date & Time	17 JUN 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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 ☐

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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"/>

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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="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"/>

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Close Date & Time](#)

22 JUL 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 JUL 2021 00:01
Patient Cloud Close Date & Time	29 JUL 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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="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"/>

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 AUG 2021 00:01
Patient Cloud Close Date & Time	19 AUG 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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="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"/>

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 390

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 SEP 2021 00:01
Patient Cloud Close Date & Time	30 SEP 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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 ☐ Yes ☐

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

03 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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"/>

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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"/>

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 OCT 2021 00:01
Patient Cloud Close Date & Time	21 OCT 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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 ☐

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 OCT 2021 00:01
Patient Cloud Close Date & Time	28 OCT 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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"/>

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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 ☐

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 NOV 2021 00:01
Patient Cloud Close Date & Time	18 NOV 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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"/>

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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="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"/>

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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"/>

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 DEC 2021 00:01
Patient Cloud Close Date & Time	23 DEC 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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 ☐

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

26 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2021 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 JAN 2022 00:01
Patient Cloud Close Date & Time	06 JAN 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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 ☐

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 JAN 2022 00:01
Patient Cloud Close Date & Time	27 JAN 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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"/>

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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 ☐

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 551

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 FEB 2022 00:01
Patient Cloud Close Date & Time	24 FEB 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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°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 ☐

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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°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 ☐

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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 ☐

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

27 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 593

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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"/>

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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"/>

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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"/>

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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"/>

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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"/>

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

15 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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="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"/>

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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="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"/>

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 JUN 2022 00:01
Patient Cloud Close Date & Time	09 JUN 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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 ☐

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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"/>

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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 ☐

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 JUN 2022 00:01
Patient Cloud Close Date & Time	30 JUN 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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"/>

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2022 00:01
Patient Cloud Close Date & Time	21 JUL 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 JUL 2022 00:01
Patient Cloud Close Date & Time	28 JUL 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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="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"/>

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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"/>

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 2022 00:01
Patient Cloud Close Date & Time	11 AUG 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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"/>

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

Patient Cloud Open Date & Time	14 AUG 2022 00:01
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Patient Cloud Close Date & Time	18 AUG 2022 23:59
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US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

Patient Cloud Open Date & Time	21 AUG 2022 00:01
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Patient Cloud Close Date & Time	25 AUG 2022 23:59
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US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 747

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

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

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

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

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

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

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

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 754

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

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

No ☐

Yes ☐

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

Fever (Temperature \geq 100.4°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 ☐

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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"/>

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

Date and time of submission	
Patient Cloud Open Date & Time	18 SEP 2022 00:01
Patient Cloud Close Date & Time	22 SEP 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

Date and time of submission	
Patient Cloud Open Date & Time	25 SEP 2022 00:01
Patient Cloud Close Date & Time	29 SEP 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

Date and time of submission	
Patient Cloud Open Date & Time	02 OCT 2022 00:01
Patient Cloud Close Date & Time	06 OCT 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

Date and time of submission	
Patient Cloud Open Date & Time	16 OCT 2022 00:01
Patient Cloud Close Date & Time	20 OCT 2022 23:59

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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"/>

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

Date and time of submission	
Patient Cloud Open Date & Time	23 OCT 2022 00:01
Patient Cloud Close Date & Time	27 OCT 2022 23:59

US3432229

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:35:54

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		04 MAR 2021 12:26:32

US3432229

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:05:48

Generated On: 09 Jun 2021 17:35:54

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 NOV 2020

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

Comments CALLED PT. 10NOV2020 A 10:08,
11NOV2020 AT 10:00, 12NOV2020
AT 10:17, AMD 16NOV2020 AT
13:52 AND 18:34. LEFT VMS AT
ALL CALLS BUT NO CONTACT
MADE.

If Contact Not Made, please provide Comments

US3432229

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:05:48

Generated On: 09 Jun 2021 17:35:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432229

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:05:27

Generated On: 09 Jun 2021 17:35:54

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments CALLED ON 12/14 @ 8:47, 12/15
@ 11:35, 12/16 10:09, 12/18 @
If Contact Not Made, please provide Comments 10:20

US3432229

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:05:27

Generated On: 09 Jun 2021 17:35:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432229

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 02:05:27

Generated On: 09 Jun 2021 17:35:54

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3432229

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 02:05:27

Generated On: 09 Jun 2021 17:35:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432229

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 20:42:10

Generated On: 09 Jun 2021 17:35:54

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

PT NOT ABLE TO BE REACHED
FOR DAY 179 SAFETY CALL. PT
WAS CALLED 17FEB21 AT 10:34,
18FEB21 AT 10:10 AND 18FEB21
AT 15:29.

US3432229

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 20:42:10

Generated On: 09 Jun 2021 17:35:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432229

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 25 Apr 2021 11:08:30

Generated On: 09 Jun 2021 17:35:54

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

Visit date (dd MMM yyyy)	22 APR 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	VISIT4
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US3432229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Apr 2021 11:08:30

Generated On: 09 Jun 2021 17:35:54

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 APR 2021
Time of assessment (00:00-23:59)	09:07 (24 HR)
Vital Signs Date and Time (derived)	22 APR 2021 09:07
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432229

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Apr 2021 11:08:30

Generated On: 09 Jun 2021 17:35:54

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.

US3432229

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Apr 2021 11:08:30

Generated On: 09 Jun 2021 17:35:54

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 APR 2021

Collection time (00:00-23:59)

09:38 (24 HR)

Collection date and time (derived)

22 APR 2021 09:38

US3432229

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 25 Apr 2021 11:08:30

Generated On: 09 Jun 2021 17:35:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432229

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 25 Apr 2021 11:08:30

Generated On: 09 Jun 2021 17:35:54

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3432229

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 25 Apr 2021 11:08:30

Generated On: 09 Jun 2021 17:35:54

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432229

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432229

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:54

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3432229

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:35:54

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"/>

US3432229

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:35:54

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3432229

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 02:05:27

Generated On: 09 Jun 2021 17:35:54

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

Visit date (dd MMM yyyy)	19 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3432229

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

Form: Unblinding

Data signed: (b) (4) 04 Apr 2021 20:42:10

Generated On: 09 Jun 2021 17:35:54

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 _____

US3432229

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 02:05:27

Generated On: 09 Jun 2021 17:35:54

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

Collection date (dd MMM yyyy)	19 JAN 2021
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Collection time (00:00-23:59)	10:51 (24 HR)
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Collection date and time (derived)	19 JAN 2021 10:51
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US3432229

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 02:05:27

Generated On: 09 Jun 2021 17:35:54

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	19 JAN 2021
Collection time (00:00 - 23:59)	10:55
Collection Date and Time (derived)	19 JAN 2021 10:55

US3432229

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 02:05:27

Generated On: 09 Jun 2021 17:35:54

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 25 Apr 2021 11:08:30

Generated On: 09 Jun 2021 17:35:54

AEID

Adverse event

TRANSIENT
GASTROINTESTINAL ILLNESS

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

04 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

05 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (1)

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

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 25 Apr 2021 11:08:30

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AEID

Adverse event

SORE THROAT

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

10 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

10 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (2)

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 25 Apr 2021 11:08:30

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AEID	USA-US078-2020-MRNA-1273-P30 1000007
Adverse event	SELF- INJURIOUS BEHAVIOR
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	17 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	30 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	24 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	30 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 25 Apr 2021 11:08:30

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

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 25 Apr 2021 11:08:30

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PARTICIPANT PRESENTED TO THE ED ON 17OCT2020 FOR SELF-INJURIOUS BEHAVIOR. HAS HISTORY OF PSYCHIATRY HOSPITALIZATION (LAST IN 2017 FOR SUICIDAL IDEATION). CURRENT EPISODE IS THOUGHT TO BE AN EXACERBATION OF TRAUMA THEY EXPERIENCED. STAYED IN ED 17-18 OCT. AND WAS TRANSFERRED TO A COMMUNITY CRISIS STABILIZATION UNIT. TRIED TO CALL PARTICIPANT TODAY, NO ANSWER. WILL FOLLOW UP.

24OCT20 - PT RE-CONSULTED IN ED FOR SELF-INJURIOUS BEHAVIOR. SYMPTOMATOLOGY AND ASSESSMENT ARE SIMILAR TO PREVIOUS ED VISIT ON 17OCT2020. BECAUSE OF RECENT FAILURE OF CCS LEVEL OF CARE, PT IS HOSPITALIZED FOR CURRENT EPISODE. ADMITTED THIS MORNING.

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 25 Apr 2021 11:08:30

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AEID	
Adverse event	LEFT EYE STYE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	17 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	20 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 25 Apr 2021 11:08:30

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AEID	
Adverse event	MILD SCOLIOSIS
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	02 APR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 04 Apr 2021 20:42:10

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 25 Apr 2021 11:08:30

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Name of Medication VYVANSE

Prophylaxis Yes ☐
No ☒

Indication ADHD

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 25 Apr 2021 11:08:30

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Name of Medication WELLBUTRIN

Prophylaxis Yes ☐
No ☒

Indication MOOD DISORDER

Dose per administration 450

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 25 Apr 2021 11:08:30

Generated On: 09 Jun 2021 17:35:54

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 25 Apr 2021 11:08:30

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Name of Medication SYMBICORT

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 25 Apr 2021 11:08:30

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	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 FEB 2020	
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)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 25 Apr 2021 11:08:30

Generated On: 09 Jun 2021 17:35:54

Name of Medication FLOVENT

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 25 Apr 2021 11:08:30

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JUN 2019	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	UN JUN 2020	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 25 Apr 2021 11:08:30

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Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication ASTHMA

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 25 Apr 2021 11:08:30

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	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)		21 AUG 2020
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 25 Apr 2021 11:08:30

Generated On: 09 Jun 2021 17:35:54

Name of Medication TESTOSTERONE

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

ONCE EVERY 9 WEEKS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 25 Apr 2021 11:08:30

Generated On: 09 Jun 2021 17:35:54

	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 NOV 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 25 Apr 2021 11:08:30

Generated On: 09 Jun 2021 17:35:54

Name of Medication MELOXICAM

Prophylaxis Yes ☐
No ☒

Indication MENSTRUAL CRAMPS

Dose per administration 14

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 25 Apr 2021 11:08:30

Generated On: 09 Jun 2021 17:35:54

	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)	22 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 23 AUG 2020		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	803 <input type="checkbox"/>
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 25 Apr 2021 11:08:30

Generated On: 09 Jun 2021 17:35:54

Name of Medication MELOXICAM

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 14

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 25 Apr 2021 11:08:30

Generated On: 09 Jun 2021 17:35:54

	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)	27 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	27 AUG 2020	
Was this medication taken for solicited event?	Yes <input checked="" type="radio"/>	
	No <input type="checkbox"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 25 Apr 2021 11:08:30

Generated On: 09 Jun 2021 17:35:54

Name of Medication MELOXICAM

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 14

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 25 Apr 2021 11:08:30

Generated On: 09 Jun 2021 17:35:54

	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)		28 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 28 AUG 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 25 Apr 2021 11:08:30

Generated On: 09 Jun 2021 17:35:54

Name of Medication SODIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication ORTHOSTATIC PRE-SYNCOPY

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 25 Apr 2021 11:08:30

Generated On: 09 Jun 2021 17:35:54

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 25 Apr 2021 11:08:30

Generated On: 09 Jun 2021 17:35:54

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication HEADACHES, PAIN AT
INJECTION SITE, 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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 25 Apr 2021 11:08:30

Generated On: 09 Jun 2021 17:35:54

	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)	19 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	20 SEP 2020	
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 25 Apr 2021 11:08:30

Generated On: 09 Jun 2021 17:35:54

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication HEADACHES, PAIN AT
INJECTION SITE, MUSCLE
ACHES.

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 25 Apr 2021 11:08:30

Generated On: 09 Jun 2021 17:35:54

	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)	19 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	20 SEP 2020	
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 25 Apr 2021 11:08:30

Generated On: 09 Jun 2021 17:35:54

Name of Medication ZOFRAN

Prophylaxis Yes ☐
No ☒

Indication TRANSIENT
GASTROINTESTINAL ILLNESS

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 25 Apr 2021 11:08:30

Generated On: 09 Jun 2021 17:35:54

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 25 Apr 2021 11:08:30

Generated On: 09 Jun 2021 17:35:54

Name of Medication ABILIFY

Prophylaxis Yes ☐
No ☒

Indication MOOD DISORDER

Dose per administration 7.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 25 Apr 2021 11:08:30

Generated On: 09 Jun 2021 17:35:54

	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)	24 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	26 OCT 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 25 Apr 2021 11:08:30

Generated On: 09 Jun 2021 17:35:54

Name of Medication ABILIFY

Prophylaxis Yes ☐
No ☒

Indication MOOD DISORDER

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 25 Apr 2021 11:08:30

Generated On: 09 Jun 2021 17:35:54

	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)	27 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 02:05:27

Generated On: 09 Jun 2021 17:35:54

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 19 Feb 2021 02:05:27

Generated On: 09 Jun 2021 17:35:54

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
2 OCT 2020	RTMS (TRANSCRANIAL MAGNETIC STIMULATION)	Medical History	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:35:54

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:35:54

Date of study discontinuation/completion (<i>dd MMM yyyy</i>)	
Reason for discontinuation	<div>AE (specify) <input type="checkbox"/></div> <div>SAE (specify) <input type="checkbox"/></div> <div>Complete <input type="checkbox"/></div> <div>Death <input type="checkbox"/></div> <div>Lost To Follow-up <input type="checkbox"/></div> <div>Physician decision (specify) <input type="checkbox"/></div> <div>Pregnancy <input type="checkbox"/></div> <div>Protocol deviation (specify) <input type="checkbox"/></div> <div>Study Terminated By Sponsor <input type="checkbox"/></div> <div>Withdrawal of consent by participant (specify) <input type="checkbox"/></div> <div>Other <input type="checkbox"/></div>
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	<div>Adverse event <input type="checkbox"/></div> <div>Unknown <input type="checkbox"/></div> <div>Other <input type="checkbox"/></div>
If main cause of death is Other, specify	
Date of death (<i>dd MMM yyyy</i>)	
Was autopsy performed?	<div>Yes <input type="checkbox"/></div> <div>No <input type="checkbox"/></div> <div>Unknown <input type="checkbox"/></div>

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Data signed: (b) (4) 19 Feb 2021 02:05:27

Generated On: 09 Jun 2021 17:35:54

SAEID	USA-US078-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Data signed: (b) (4) 19 Feb 2021 02:05:27

Generated On: 09 Jun 2021 17:35:54

SAEID	USA-US078-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	20/OCT/2020 19:09
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Data signed: (b) (4) 19 Feb 2021 02:05:27

Generated On: 09 Jun 2021 17:35:54

SAEID	USA-US078-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	26/OCT/2020 16:01
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Data signed: (b) (4) 19 Feb 2021 02:05:27

Generated On: 09 Jun 2021 17:35:54

SAEID	USA-US078-2020-MRNA-1273-P301000007
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	3
Date of submission (Pre-filled from custom function)	09/NOV/2020 07:37
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3432229 (Prod: Brigham and Womens Hospital)

US3432229

Form: Participant Creation

Generated On: 09 Jun 2021 17:35:54

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'US3432229'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 14:39:29

US3432229

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:35:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	21 Aug 2020 15:58:57

US3432229

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '21 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 14:39:30

US3432229

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:35:54

[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 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Clinic (Clinic)'	Xhoi Mitre (b) (4)	21 Aug 2020 15:58:57

US3432229

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:35:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User entered 'SCRN'	System	21 Aug 2020 15:58:57

US3432229

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:54

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered (b) (6) 1996'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 14:39:31

US3432229

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:54

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '24'	Xhoi Mitre (b) (4)	21 Aug 2020 16:00:25

US3432229

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:54

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User entered 'YEARS'	System	21 Aug 2020 16:00:25

US3432229

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:54

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User entered '24'	System	21 Aug 2020 16:01:09

US3432229

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:54

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Female (F)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:00:25

US3432229

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:54

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:00:25

US3432229

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:54

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'I'	Xhoi Mitre (b) (4)	21 Aug 2020 16:00:25

US3432229

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:54

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '0'	Xhoi Mitre (b) (4)	21 Aug 2020 16:00:25

US3432229

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:54

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '0'	Xhoi Mitre (b) (4)	21 Aug 2020 16:00:25

US3432229

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:54

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '0'	Xhoi Mitre (b) (4)	21 Aug 2020 16:00:25

US3432229

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:54

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '0'	Xhoi Mitre (b) (4)	21 Aug 2020 16:00:25

US3432229

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:54

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '0'	Xhoi Mitre (b) (4)	21 Aug 2020 16:00:25

US3432229

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:54

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty.	Xhoi Mitre (b) (4)	21 Aug 2020 16:00:25

US3432229

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:54

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '0'	Xhoi Mitre (b) (4)	21 Aug 2020 16:00:25

US3432229

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:35:54

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '0'	Xhoi Mitre (b) (4)	21 Aug 2020 16:00:25

US3432229

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:35:54

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '21 Aug 2020'	Xhoi Mitre (b) (4)	21 Aug 2020 16:01:09

US3432229

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User entered 'Aug 2020'	System	21 Aug 2020 16:01:09

US3432229

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User entered '2020'	System	21 Aug 2020 16:01:09

US3432229

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:35:54

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Amendment 2 (2)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:01:09

US3432229

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:01:09

US3432229

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:35:54

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty.	Xhoi Mitre (b) (4)	21 Aug 2020 16:01:09

US3432229

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:35:54

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty.	Xhoi Mitre (b) (4)	21 Aug 2020 16:01:09

US3432229

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:35:54

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'No (N)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:01:09

US3432229

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:35:54

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 14:39:30

US3432229

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:35:54

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User entered 'I'	System	21 Aug 2020 16:01:14

US3432229

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:01:14

US3432229

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:35:54

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:44:20

US3432229

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:35:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User coded data point as SOC: Psychiatric disorders, HLGT: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: ADHD - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 16:45:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 16:45:14
Data point term sent to Coder	System	21 Aug 2020 16:44:50
User entered 'ADHD'	Xhoi Mitre (b) (4)	21 Aug 2020 16:44:37

US3432229

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'UN UNK 2016'	Xhoi Mitre (b) (4)	21 Aug 2020 16:44:37

US3432229

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '0'	Xhoi Mitre (b) (4)	21 Aug 2020 16:44:37

US3432229

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:35:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:44:37

US3432229

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty.	Xhoi Mitre (b) (4)	21 Aug 2020 16:44:37

US3432229

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:35:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '0'	Xhoi Mitre (b) (4)	21 Aug 2020 16:44:37

US3432229

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User entered 'Jan 2016'	System	21 Aug 2020 16:44:37

US3432229

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User entered '2016'	System	21 Aug 2020 16:44:37

US3432229

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User entered empty.	System	21 Aug 2020 16:44:37

US3432229

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User entered empty.	System	21 Aug 2020 16:44:37

US3432229

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:35:54

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User coded data point as SOC: Psychiatric disorders, HLTG: Mood disorders and disturbances NEC, HLT: Mood disorders NEC, PT: Affective disorder, LLT: Mood disorder - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 16:46:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Aug 2020 16:46:16
Data point term sent to Coder	System	21 Aug 2020 16:45:52
User entered 'Mood Disorder'	Xhoi Mitre (b) (4)	21 Aug 2020 16:44:55

US3432229

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'UN UNK 2009'	Xhoi Mitre (b) (4)	21 Aug 2020 16:44:55

US3432229

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '0'	Xhoi Mitre (b) (4)	21 Aug 2020 16:44:55

US3432229

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:35:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:44:55

US3432229

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty.	Xhoi Mitre (b) (4)	21 Aug 2020 16:44:55

US3432229

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:35:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '0'	Xhoi Mitre (b) (4)	21 Aug 2020 16:44:55

US3432229

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User entered 'Jan 2009'	System	21 Aug 2020 16:44:55

US3432229

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User entered '2009'	System	21 Aug 2020 16:44:55

US3432229

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User entered empty.	System	21 Aug 2020 16:44:55

US3432229

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User entered empty.	System	21 Aug 2020 16:44:55

US3432229

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:35:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
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)	21 Aug 2020 16:46:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Aug 2020 16:46:17
Data point term sent to Coder	System	21 Aug 2020 16:45:54
User entered 'Asthma'	Xhoi Mitre (b) (4)	21 Aug 2020 16:45:15

US3432229

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'UN UNK 1998'	Xhoi Mitre (b) (4)	21 Aug 2020 16:45:15

US3432229

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '0'	Xhoi Mitre (b) (4)	21 Aug 2020 16:45:15

US3432229

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:35:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:45:15

US3432229

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty.	Xhoi Mitre (b) (4)	21 Aug 2020 16:45:15

US3432229

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:35:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '0'	Xhoi Mitre (b) (4)	21 Aug 2020 16:45:15

US3432229

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User entered 'Jan 1998'	System	21 Aug 2020 16:45:15

US3432229

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User entered '1998'	System	21 Aug 2020 16:45:15

US3432229

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User entered empty.	System	21 Aug 2020 16:45:15

US3432229

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User entered empty.	System	21 Aug 2020 16:45:15

US3432229

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:35:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Presyncope, LLT: Pre-syncope - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 13:20:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 13:20:58
User closed query 'Per CDM: Per previous query response "Updated"; however, the update is not obvious please provide location of update such as log line number. Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 07:49:12
Query 'Per CDM: Per previous query response "Updated"; however, the update is not obvious please provide location of update such as log line number. Thank you. ' answered with 'updated within entry' (Site from DM).	Julia Klopfer (b) (4)	10 Nov 2020 21:53:38
User closed query 'Per DM CLR: Only one medical condition should be entered per line. Please update MH term to indicate a single underlying condition or split events and record them as a different condition (MH# 06). ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 08:05:28
User opened query 'Per CDM: Per previous query response "Updated"; however, the update is not obvious please provide location of update such as log line number. Thank you. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 08:05:25
Data point term sent to Coder	System	22 Oct 2020 00:18:42
Query 'Per DM CLR: Only one medical condition should be entered per line. Please update MH term to indicate a single underlying condition or split events and record them as a different condition (MH# 06). ' answered with 'updated' (Site from DM).	Julia Klopfer (b) (4)	22 Oct 2020 00:18:00
Coding entries removed.	Julia Klopfer (b) (4)	22 Oct 2020 00:17:49
User entered 'ORTHOSTATIC PRE-SYNCOPE' reason for change: Data Entry Error	Julia Klopfer (b) (4)	22 Oct 2020 00:17:49

US3432229

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:35:54

Condition

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Only one medical condition should be entered per line. Please update MH term to indicate a single underlying condition or split events and record them as a different condition (MH# 06). ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 17:23:03
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Presyncope, LLT: Orthostatic presyncope - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 09:14:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Sep 2020 09:14:42
Data point term sent to Coder	System	18 Sep 2020 16:10:19
User entered 'Pre-syncope/orthostatic'	Bruce Bausk (b) (4) (b) (4)	18 Sep 2020 16:10:12

US3432229

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'un UNK 2009'	Bruce Bausk (b) (4)	18 Sep 2020 16:10:12

US3432229

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '0'	Bruce Bausk (b) (4)	18 Sep 2020 16:10:12

US3432229

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:35:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	18 Sep 2020 16:10:12

US3432229

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty.	Bruce Bausk (b) (4)	18 Sep 2020 16:10:12

US3432229

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:35:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '0'	Bruce Bausk (b) (4)	18 Sep 2020 16:10:12

US3432229

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:35:54

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User entered 'Jan 2009'	System	18 Sep 2020 16:10:12

US3432229

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:35:54

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User entered '2009'	System	18 Sep 2020 16:10:12

US3432229

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User entered empty.	System	18 Sep 2020 16:10:12

US3432229

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User entered empty.	System	18 Sep 2020 16:10:12

US3432229

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:35:54

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User coded data point as SOC: Reproductive system and breast disorders, HLG: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation and uterine bleeding NEC, PT: Dysmenorrhoea, LLT: Dysmenorrhea - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 16:13:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Sep 2020 16:13:59
Data point term sent to Coder	System	18 Sep 2020 16:12:23
User entered 'Dysmenorrhea'	Bruce Bausk (b) (4)	18 Sep 2020 16:11:28

US3432229

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'un UNK 2008'	Bruce Bausk (b) (4)	18 Sep 2020 16:11:28

US3432229

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '0'	Bruce Bausk (b) (4)	18 Sep 2020 16:11:28

US3432229

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:35:54

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	18 Sep 2020 16:11:28

US3432229

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty.	Bruce Bausk (b) (4)	18 Sep 2020 16:11:28

US3432229

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:35:54

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '0'	Bruce Bausk (b) (4)	18 Sep 2020 16:11:28

US3432229

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User entered 'Jan 2008'	System	18 Sep 2020 16:11:28

US3432229

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User entered '2008'	System	18 Sep 2020 16:11:28

US3432229

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User entered empty.	System	18 Sep 2020 16:11:28

US3432229

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User entered empty.	System	18 Sep 2020 16:11:28

US3432229

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:36:31

US3432229

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '21 Aug 2020'	Xhoi Mitre (b) (4)	21 Aug 2020 16:36:31

US3432229

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '10:32'	Xhoi Mitre (b) (4)	21 Aug 2020 16:36:31

US3432229

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User entered '21 Aug 2020 10:32'	System	21 Aug 2020 16:36:31

US3432229

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '159.1' cm	Xhoi Mitre (b) (4)	21 Aug 2020 16:36:31
DataPoint set to visible.	(b) (4) System	21 Aug 2020 16:01:14

US3432229

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '067.2' kg	Xhoi Mitre (b) (4)	21 Aug 2020 16:36:31
DataPoint set to visible.	(b) (4) System	21 Aug 2020 16:01:14

US3432229

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
Amendment Manager: User entered '26.54782'	System	17 Sep 2020 00:17:58
User entered '26.5'	System	21 Aug 2020 16:36:31
DataPoint set to visible.	System	21 Aug 2020 16:01:14

US3432229

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User entered 'kg/m2'	System	21 Aug 2020 16:36:31
DataPoint set to visible.	System	21 Aug 2020 16:01:14

US3432229

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered missing code ND - Not Done.	Xhoi Mitre (b) (4)	21 Aug 2020 16:36:31

US3432229

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty.	Xhoi Mitre (b) (4)	21 Aug 2020 16:36:31

US3432229

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty.	Xhoi Mitre (b) (4)	21 Aug 2020 16:36:31

US3432229

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered missing code ND - Not Done.	Xhoi Mitre (b) (4)	21 Aug 2020 16:36:31

US3432229

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User entered 'bpm'	System	21 Aug 2020 16:36:31

US3432229

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered missing code ND - Not Done.	Xhoi Mitre (b) (4)	21 Aug 2020 16:36:31

US3432229

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User entered 'breaths/min'	System	21 Aug 2020 16:36:31

US3432229

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered missing code ND - Not Done.	Xhoi Mitre (b) (4)	21 Aug 2020 16:36:31

US3432229

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User entered 'mmHg'	System	21 Aug 2020 16:36:31

US3432229

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered missing code ND - Not Done.	Xhoi Mitre (b) (4)	21 Aug 2020 16:36:31

US3432229

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User entered 'mmHg'	System	21 Aug 2020 16:36:31

US3432229

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49

US3432229

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49

US3432229

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:35:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:33:02

US3432229

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:35:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '21 Aug 2020'	Xhoi Mitre (b) (4)	21 Aug 2020 16:33:02

US3432229

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:35:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '21 Aug 2020'	Xhoi Mitre (b) (4)	21 Aug 2020 16:33:40

US3432229

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:35:54

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:33:40

US3432229

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty.	Xhoi Mitre (b) (4)	21 Aug 2020 16:33:40

US3432229

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:35:54

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty.	Xhoi Mitre (b) (4)	21 Aug 2020 16:33:40

US3432229

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty.	Xhoi Mitre (b) (4)	21 Aug 2020 16:33:40

US3432229

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:35:54

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '0'	Xhoi Mitre (b) (4)	21 Aug 2020 16:33:40

US3432229

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty.	Xhoi Mitre (b) (4)	21 Aug 2020 16:33:40

US3432229

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:35:54

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '0'	Xhoi Mitre (b) (4)	21 Aug 2020 16:33:40

US3432229

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:35:54

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:34:12

US3432229

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:35:54

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '21 Aug 2020'	Xhoi Mitre (b) (4)	21 Aug 2020 16:34:12

US3432229

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:35:54

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Urine (URINE)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:34:12

US3432229

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:35:54

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Negative (NEGATIVE)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:34:12

US3432229

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:35:54

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'No (N)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:34:12

US3432229

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:35:54

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty.	Xhoi Mitre (b) (4)	21 Aug 2020 16:34:12

US3432229

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:35:54

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty.	Xhoi Mitre (b) (4)	21 Aug 2020 16:34:12

US3432229

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User entered empty.	System	21 Aug 2020 16:34:12

US3432229

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:54

[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 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'No (N)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:35:20

US3432229

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:54

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 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'No (N)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:35:20

US3432229

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:54

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 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'No (N)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:35:20

US3432229

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:54

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 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'No (N)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:35:20

US3432229

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:54

[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 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'No (N)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:35:20

US3432229

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:54

[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 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'No (N)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:35:20

US3432229

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:54

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 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'No (N)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:35:20

US3432229

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:54

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 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'No (N)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:35:20

US3432229

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:54

[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 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'No (N)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:35:20

US3432229

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:54

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 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:35:20

US3432229

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:54

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 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'No (N)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:35:20

US3432229

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:54

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'No (N)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:35:20

US3432229

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:54

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty.	Xhoi Mitre (b) (4)	21 Aug 2020 16:35:20

US3432229

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:54

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '0'	Xhoi Mitre (b) (4)	21 Aug 2020 16:35:20

US3432229

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:54

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '0'	Xhoi Mitre (b) (4)	21 Aug 2020 16:35:20

US3432229

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:54

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 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '0'	Xhoi Mitre (b) (4)	21 Aug 2020 16:35:20

US3432229

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:54

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 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'I'	Xhoi Mitre (b) (4)	21 Aug 2020 16:35:20

US3432229

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:54

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 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '0'	Xhoi Mitre (b) (4)	21 Aug 2020 16:35:20

US3432229

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:54

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '0'	Xhoi Mitre (b) (4)	21 Aug 2020 16:35:20

US3432229

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:54

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '0'	Xhoi Mitre (b) (4)	21 Aug 2020 16:35:20

US3432229

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:35:54

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty.	Xhoi Mitre (b) (4)	21 Aug 2020 16:35:20

US3432229

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:35:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:01:47

US3432229

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:35:54

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '21 Aug 2020'	Xhoi Mitre (b) (4)	21 Aug 2020 16:01:47

US3432229

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:35:54

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Clinic (Clinic)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:01:47

US3432229

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:35:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'VISIT1'	System	21 Aug 2020 16:01:47

US3432229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '21 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 15:29:49

US3432229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:35:54

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '144547'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 15:29:49

US3432229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:35:54

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	21 Aug 2020 15:29:49

US3432229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:35:54

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)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:31:41

US3432229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:35:54

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)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'No (N)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:31:41

US3432229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:35:54

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'No (N)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:31:41

US3432229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:35:54

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'No (N)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:31:41

US3432229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:35:54

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'No (N)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:31:41

US3432229

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:35:54

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:38:04
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:57:52

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:35:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered missing code ND - Not Done.	Xhoi Mitre (b) (4)	21 Aug 2020 22:09:47

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:35:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered missing code ND - Not Done.	Xhoi Mitre (b) (4)	21 Aug 2020 22:09:47

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:35:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered missing code ND - Not Done.	Xhoi Mitre (b) (4)	21 Aug 2020 22:09:47

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:35:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered missing code ND - Not Done.	Xhoi Mitre (b) (4)	21 Aug 2020 22:09:47

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User accepted default value 'Pre-Dose (PREDOSE)'	Xhoi Mitre (b) (4) (b) (4)	21 Aug 2020 22:09:47

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	21 Aug 2020 22:09:47

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '21 Aug 2020'	Xhoi Mitre (b) (4)	21 Aug 2020 22:09:47

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '10:32'	Xhoi Mitre (b) (4)	21 Aug 2020 22:09:47

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered '21 Aug 2020 10:32'	System	21 Aug 2020 22:09:47

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '36.5' C	Xhoi Mitre (b) (4)	21 Aug 2020 22:09:47

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Oral (Oral)'	Xhoi Mitre (b) (4)	21 Aug 2020 22:09:47

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty.	Xhoi Mitre (b) (4)	21 Aug 2020 22:09:47

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '077'	Xhoi Mitre (b) (4)	21 Aug 2020 22:09:47

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'bpm'	System	21 Aug 2020 22:09:47

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '10'	Xhoi Mitre (b) (4)	21 Aug 2020 22:09:47

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'breaths/min'	System	21 Aug 2020 22:09:47

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '121'	Xhoi Mitre (b) (4)	21 Aug 2020 22:09:47

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'mmHg'	System	21 Aug 2020 22:09:47

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '069'	Xhoi Mitre (b) (4)	21 Aug 2020 22:09:47

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'mmHg'	System	21 Aug 2020 22:09:47

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:35:54

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered missing code ND - Not Done.	Xhoi Mitre (b) (4)	21 Aug 2020 22:09:47

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:35:54

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered missing code ND - Not Done.	Xhoi Mitre (b) (4)	21 Aug 2020 22:09:47

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User accepted default value 'Post-Dose (POSTDOSE)'	Xhoi Mitre (b) (4) (b) (4)	21 Aug 2020 22:09:47

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	21 Aug 2020 22:09:47

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '21 Aug 2020'	Xhoi Mitre (b) (4)	21 Aug 2020 22:09:47

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '13:26'	Xhoi Mitre (b) (4)	21 Aug 2020 22:09:47

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered '21 Aug 2020 13:26'	System	21 Aug 2020 22:09:47

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '37.1' C	Xhoi Mitre (b) (4)	21 Aug 2020 22:09:47

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Oral (Oral)'	Xhoi Mitre (b) (4)	21 Aug 2020 22:09:47

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty.	Xhoi Mitre (b) (4)	21 Aug 2020 22:09:47

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '073'	Xhoi Mitre (b) (4)	21 Aug 2020 22:09:47

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'bpm'	System	21 Aug 2020 22:09:47

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '14'	Xhoi Mitre (b) (4)	21 Aug 2020 22:09:47

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'breaths/min'	System	21 Aug 2020 22:09:47

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '124'	Xhoi Mitre (b) (4)	21 Aug 2020 22:09:47

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'mmHg'	System	21 Aug 2020 22:09:47

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '075'	Xhoi Mitre (b) (4)	21 Aug 2020 22:09:47

US3432229

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'mmHg'	System	21 Aug 2020 22:09:47

US3432229

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:35:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'No (N)' reason for change: Data Entry Error	Xhoi Mitre (b) (4)	21 Aug 2020 16:32:46
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:32:26

US3432229

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:35:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty; reason for change Data Entry Error	Xhoi Mitre (b) (4)	21 Aug 2020 16:32:46
User entered '21 Aug 2020'	Xhoi Mitre (b) (4)	21 Aug 2020 16:32:26

US3432229

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:35:54

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User closed query 'Per CDM, test with the same date reported at Screening. Please check. If duplicate information, please record test at Visit 1 Day 1 as not performed, otherwise explain.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 08:02:29
Query 'Per CDM, test with the same date reported at Screening. Please check. If duplicate information, please record test at Visit 1 Day 1 as not performed, otherwise explain.' answered with 'This is against EDC guidelines' (Site from DM).	Alexander Mills (b) (4)	22 Oct 2020 17:31:34
User entered 'No (N)' reason for change: Data Entry Error	Alexander Mills (b) (4)	22 Oct 2020 17:30:28
User opened query 'Per CDM, test with the same date reported at Screening. Please check. If duplicate information, please record test at Visit 1 Day 1 as not performed, otherwise explain.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 14:47:37
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:45:34

US3432229

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:35:54

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty; reason for change Data Entry Error	Alexander Mills (b) (4)	22 Oct 2020 17:30:28
User entered '21 Aug 2020'	Xhoi Mitre (b) (4)	21 Aug 2020 16:45:34

US3432229

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:35:54

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty; reason for change Data Entry Error	Alexander Mills (b) (4)	22 Oct 2020 17:30:28
User entered 'Urine (URINE)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:45:34

US3432229

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:35:54

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty; reason for change Data Entry Error	Alexander Mills (b) (4)	22 Oct 2020 17:30:28
User entered 'Negative (NEGATIVE)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:45:34

US3432229

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:35:54

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User closed query 'Per CDM: A response Yes/No is required for this field. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 08:04:24
Query 'Per CDM: A response Yes/No is required for this field. Please update accordingly. ' answered with 'updated' (Site from DM).	Julia Klopfer (b) (4)	06 Nov 2020 18:37:23
User entered 'No (N)' reason for change: Data Entry Error	Julia Klopfer (b) (4)	06 Nov 2020 18:37:17
User opened query 'Per CDM: A response Yes/No is required for this field. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 08:02:38
User entered empty; reason for change Data Entry Error	Alexander Mills (b) (4)	22 Oct 2020 17:30:28
User entered 'No (N)'	Xhoi Mitre (b) (4)	21 Aug 2020 16:45:34

US3432229

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:35:54

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty.	Xhoi Mitre (b) (4)	21 Aug 2020 16:45:34

US3432229

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:35:54

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty.	Xhoi Mitre (b) (4)	21 Aug 2020 16:45:34

US3432229

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered empty.	System	21 Aug 2020 16:45:34

US3432229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:35:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	21 Aug 2020 17:08:42

US3432229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:35:54

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty.	Xhoi Mitre (b) (4)	21 Aug 2020 17:08:42

US3432229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty.	Xhoi Mitre (b) (4)	21 Aug 2020 17:08:42

US3432229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:35:54

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'MRNA-1273 OR PLACEBO'	System	21 Aug 2020 17:08:42

US3432229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:35:54

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '21 Aug 2020'	Xhoi Mitre (b) (4)	21 Aug 2020 17:08:42

US3432229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:35:54

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '12:56'	Xhoi Mitre (b) (4)	21 Aug 2020 17:08:42

US3432229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:35:54

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered '21 Aug 2020 12:56'	System	21 Aug 2020 17:08:42

US3432229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:35:54

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Left Arm (LEFT ARM)'	Xhoi Mitre (b) (4)	21 Aug 2020 17:08:42

US3432229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:35:54

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'ONCE'	System	21 Aug 2020 17:08:42

US3432229

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:35:54

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'INTRAMUSCULAR'	System	21 Aug 2020 17:08:42

US3432229

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	21 Aug 2020 21:44:23

US3432229

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '21 Aug 2020'	Xhoi Mitre (b) (4)	21 Aug 2020 21:44:23

US3432229

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:54

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '11:00' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 18:06:58
User entered '11:27'	Xhoi Mitre (b) (4)	21 Aug 2020 21:44:23

US3432229

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered '21 Aug 2020 11:00'	System	28 Sep 2020 18:06:58
User entered '21 Aug 2020 11:27'	System	21 Aug 2020 21:44:23

US3432229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:35:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '21 Aug 2020'	Xhoi Mitre (b) (4)	21 Aug 2020 21:44:46

US3432229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:35:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Xhoi Mitre (b) (4) (b) (4)	21 Aug 2020 21:44:46

US3432229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:35:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	21 Aug 2020 21:44:46

US3432229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:35:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '11:05' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Sep 2020 18:07:06
User entered '11:32'	Xhoi Mitre (b) (4)	21 Aug 2020 21:44:46

US3432229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered '21 Aug 2020 11:05'	System	28 Sep 2020 18:07:06
User entered '21 Aug 2020 11:32'	System	21 Aug 2020 21:44:46

US3432229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:35:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Xhoi Mitre (b) (4) (b) (4)	21 Aug 2020 21:44:46

US3432229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:35:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'No (N)'	Xhoi Mitre (b) (4)	21 Aug 2020 21:44:46

US3432229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:35:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty.	Xhoi Mitre (b) (4)	21 Aug 2020 21:44:46

US3432229

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:35:54

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered empty.	System	21 Aug 2020 21:44:46

US3432229

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:35:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	21 Aug 2020 21:44:51

US3432229

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:35:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'I'	System	21 Aug 2020 21:44:51

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
Data entry locked.	System	21 Aug 2020 17:08:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T13:30:42', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '07fb2627-40bc-47b5-a10a-2971e14694e3' User entered 'Yes (Y)'	System	21 Aug 2020 17:31:05
	System	21 Aug 2020 17:31:05

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T13:30:50', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '07fb2627-40bc-47b5-a10a-2971e14694e3' User entered '98.8'	System	21 Aug 2020 17:31:05
	System	21 Aug 2020 17:31:05

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T13:30:54', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '07fb2627-40bc-47b5-a10a-2971e14694e3'	System	21 Aug 2020 17:31:05
User entered 'No (N)'	System	21 Aug 2020 17:31:05

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T13:31:00', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '07fb2627-40bc-47b5-a10a-2971e14694e3' User entered '21 Aug 2020 13:31'	System	21 Aug 2020 17:31:05
	System	21 Aug 2020 17:31:05

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '21 Aug 2020 13:16'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '21 Aug 2020 15:46'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
Data entry locked.	System	21 Aug 2020 17:08:42
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T16:50:09', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '2a9b15d5-20e8-49c7-ad3d-cd0becda0268' User entered 'Yes (Y)'	System	21 Aug 2020 20:50:23
	System	21 Aug 2020 20:50:23

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T16:50:14', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '2a9b15d5-20e8-49c7-ad3d-cd0becda0268' User entered '98.6'	System	21 Aug 2020 20:50:23
	System	21 Aug 2020 20:50:23

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T16:50:16', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '2a9b15d5-20e8-49c7-ad3d-cd0becda0268' User entered 'No (N)'	System	21 Aug 2020 20:50:23
	System	21 Aug 2020 20:50:23

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T16:50:20', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '2a9b15d5-20e8-49c7-ad3d-cd0becda0268' User entered '21 Aug 2020 16:50'	System	21 Aug 2020 20:50:23
	System	21 Aug 2020 20:50:23

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '21 Aug 2020 16:41'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
Data entry locked.	System	21 Aug 2020 17:08:42
User entered 'Day 2'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-22T18:39:48', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6b71e39f-9071-4466-a728-723d71c23aee' User entered 'Yes (Y)'	System	22 Aug 2020 22:40:09
	System	22 Aug 2020 22:40:09

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-22T18:39:53', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6b71e39f-9071-4466-a728-723d71c23aee' User entered '98.3'	System	22 Aug 2020 22:40:09
	System	22 Aug 2020 22:40:09

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-22T18:39:57', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6b71e39f-9071-4466-a728-723d71c23aee' User entered 'Yes (Y)'	System	22 Aug 2020 22:40:09
	System	22 Aug 2020 22:40:09

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
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 'participant contacted and meloxicam noted in the e-diary' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 09:01:59
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).	Phoebe Cunningham	05 Sep 2020 14:17:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-22T18:40:03', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6b71e39f-9071-4466-a728-723d71c23aee'	(b) (4)	
User entered '1'	System	22 Aug 2020 22:40:09
	System	22 Aug 2020 22:40:09
	System	22 Aug 2020 22:40:09

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:54

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-22T18:40:03', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6b71e39f-9071-4466-a728-723d71c23aee' User entered '0'	System	22 Aug 2020 22:40:09
	System	22 Aug 2020 22:40:09

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-22T18:40:05', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6b71e39f-9071-4466-a728-723d71c23aee' User entered '22 Aug 2020 18:40'	System	22 Aug 2020 22:40:09
	System	22 Aug 2020 22:40:09

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
Data entry locked.	System	21 Aug 2020 17:08:42
User entered 'Day 3'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T10:48:00', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '700ade04-cd34-4a3e-85e3-3bf6b95aca5d' User entered 'Yes (Y)'	System	24 Aug 2020 14:48:25
	System	24 Aug 2020 14:48:25

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T10:48:04', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '700ade04-cd34-4a3e-85e3-3bf6b95aca5d' User entered '98.3'	System	24 Aug 2020 14:48:25
	System	24 Aug 2020 14:48:25

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T10:48:11', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '700ade04-cd34-4a3e-85e3-3bf6b95aca5d'	System	24 Aug 2020 14:48:25
User entered 'Yes (Y)'	System	24 Aug 2020 14:48:25

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
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 'participant contacted and meloxicam noted in the e-diary' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 09:02:20
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T10:48:21', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '700ade04-cd34-4a3e-85e3-3bf6b95aca5d' User entered '1'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:17:14
	System	24 Aug 2020 14:48:25
	System	24 Aug 2020 14:48:25
	System	24 Aug 2020 14:48:25

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:54

To PREVENT pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'participant contacted and meloxicam noted in the e-diary' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 09:02:26
User opened query 'Per the participant response, medication was taken to prevent 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).	Phoebe Cunningham (b) (4)	05 Sep 2020 14:17:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T10:48:21', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '700ade04-cd34-4a3e-85e3-3bf6b95aca5d'	System	24 Aug 2020 14:48:25
User entered '1'	System	24 Aug 2020 14:48:25

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T10:48:23', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '700ade04-cd34-4a3e-85e3-3bf6b95aca5d' User entered '24 Aug 2020 10:48'	System	24 Aug 2020 14:48:25
	System	24 Aug 2020 14:48:25

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
Data entry locked.	System	21 Aug 2020 17:08:42
User entered 'Day 4'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T22:39:34', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '9444a6f7-0faa-473c-abef-1781c665319c' User entered 'Yes (Y)'	System	25 Aug 2020 02:40:32
	System	25 Aug 2020 02:40:32

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T22:40:26', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '9444a6f7-0faa-473c-abef-1781c665319c' User entered '98.3'	System	25 Aug 2020 02:40:32
	System	25 Aug 2020 02:40:32

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T22:40:28', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '9444a6f7-0faa-473c-abef-1781c665319c' User entered 'No (N)'	System	25 Aug 2020 02:40:32
	System	25 Aug 2020 02:40:32

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T22:40:30', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '9444a6f7-0faa-473c-abef-1781c665319c' User entered '24 Aug 2020 22:40'	System	25 Aug 2020 02:40:32
	System	25 Aug 2020 02:40:32

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
Data entry locked.	System	21 Aug 2020 17:08:42
User entered 'Day 5'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-25T22:43:05', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'b3aaeca1-29c2-46f2-8360-1674c148981f' User entered 'Yes (Y)'	System	26 Aug 2020 02:43:29
	System	26 Aug 2020 02:43:29

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-25T22:43:18', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'b3aaeca1-29c2-46f2-8360-1674c148981f' User entered '98.3'	System	26 Aug 2020 02:43:29
	System	26 Aug 2020 02:43:29

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-25T22:43:22', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'b3aaeca1-29c2-46f2-8360-1674c148981f' User entered 'No (N)'	System	26 Aug 2020 02:43:29
	System	26 Aug 2020 02:43:29

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-25T22:43:26', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'b3aaeca1-29c2-46f2-8360-1674c148981f' User entered '25 Aug 2020 22:43'	System	26 Aug 2020 02:43:29
	System	26 Aug 2020 02:43:29

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
Data entry locked.	System	21 Aug 2020 17:08:42
User entered 'Day 6'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T07:55:26', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ddb38b4-5108-4fac-80ff-f582102c0d77'	System	27 Aug 2020 11:55:43
User entered 'Yes (Y)'	System	27 Aug 2020 11:55:43

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T07:55:30', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ddb38b4-5108-4fac-80ff-f582102c0d77'	System	27 Aug 2020 11:55:43
User entered '98.3'	System	27 Aug 2020 11:55:43

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T07:55:34', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ddb38b4-5108-4fac-80ff-f582102c0d77'	System	27 Aug 2020 11:55:43
User entered 'Yes (Y)'	System	27 Aug 2020 11:55:43

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
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 'participant contacted and meloxicam noted in the e-diary' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 09:02:39
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T07:55:36', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ddb38b4-5108-4fac-80ff-f582102c0d77'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:17:03
User entered '1'	System	27 Aug 2020 11:55:43
	System	27 Aug 2020 11:55:43
	System	27 Aug 2020 11:55:43

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:54

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T07:55:36', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ddb38b4-5108-4fac-80ff-f582102c0d77'	System	27 Aug 2020 11:55:43
User entered '0'	System	27 Aug 2020 11:55:43

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T07:55:38', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ddb38b4-5108-4fac-80ff-f582102c0d77'	System	27 Aug 2020 11:55:43
User entered '27 Aug 2020 07:55'	System	27 Aug 2020 11:55:43

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
Data entry locked.	System	21 Aug 2020 17:08:42
User entered 'Day 7'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T23:59:30', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ebb93ed9-51ea-46da-b555-e61112d794a7' User entered 'Yes (Y)'	System	28 Aug 2020 03:59:44
	System	28 Aug 2020 03:59:44

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T23:59:36', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ebb93ed9-51ea-46da-b555-e61112d794a7' User entered '98.3'	System	28 Aug 2020 03:59:44
	System	28 Aug 2020 03:59:44

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T23:59:39', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ebb93ed9-51ea-46da-b555-e61112d794a7'	System	28 Aug 2020 03:59:44
User entered 'No (N)'	System	28 Aug 2020 03:59:44

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T23:59:41', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ebb93ed9-51ea-46da-b555-e61112d794a7' User entered '27 Aug 2020 23:59'	System	28 Aug 2020 03:59:44
	System	28 Aug 2020 03:59:44

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
Data entry locked.	System	21 Aug 2020 17:08:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T13:31:10', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '71a08012-5163-42e0-92f1-cf464a0763e0'	System	21 Aug 2020 17:34:34
User entered 'Does not interfere with activity (2)'	System	21 Aug 2020 17:34:34

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T13:31:20', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '71a08012-5163-42e0-92f1-cf464a0763e0' User entered 'Yes (Y)'	System	21 Aug 2020 17:34:34
	System	21 Aug 2020 17:34:34

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T13:32:59', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '71a08012-5163-42e0-92f1-cf464a0763e0' User entered '53'	System	21 Aug 2020 17:34:34
	System	21 Aug 2020 17:34:34

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T13:33:09', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '71a08012-5163-42e0-92f1-cf464a0763e0' User entered 'Yes (Y)'	System	21 Aug 2020 17:34:34
	System	21 Aug 2020 17:34:34

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T13:33:57', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '71a08012-5163-42e0-92f1-cf464a0763e0' User entered '5'	System	21 Aug 2020 17:34:34
	System	21 Aug 2020 17:34:34

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T13:34:04', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '71a08012-5163-42e0-92f1-cf464a0763e0' User entered 'None (1)'	System	21 Aug 2020 17:34:34
	System	21 Aug 2020 17:34:34

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T13:34:08', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '71a08012-5163-42e0-92f1-cf464a0763e0' User entered '21 Aug 2020 13:34'	System	21 Aug 2020 17:34:34
	System	21 Aug 2020 17:34:34

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '21 Aug 2020 13:16'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '21 Aug 2020 15:46'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
Data entry locked.	System	21 Aug 2020 17:08:42
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T16:51:08', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bf98b21a-3918-4478-80cc-8c90d85caa38'	System	21 Aug 2020 20:52:27
User entered 'Does not interfere with activity (2)'	System	21 Aug 2020 20:52:27

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T16:52:00', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bf98b21a-3918-4478-80cc-8c90d85caa38' User entered 'No (N)'	System	21 Aug 2020 20:52:27
	System	21 Aug 2020 20:52:27

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T16:52:08', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bf98b21a-3918-4478-80cc-8c90d85caa38' User entered 'No (N)'	System	21 Aug 2020 20:52:27
	System	21 Aug 2020 20:52:27

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T16:52:21', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bf98b21a-3918-4478-80cc-8c90d85caa38'	System	21 Aug 2020 20:52:27
User entered 'Does not interfere with activity (2)'	System	21 Aug 2020 20:52:27

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T16:52:24', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bf98b21a-3918-4478-80cc-8c90d85caa38' User entered '21 Aug 2020 16:52'	System	21 Aug 2020 20:52:27
	System	21 Aug 2020 20:52:27

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '21 Aug 2020 16:41'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
Data entry locked.	System	21 Aug 2020 17:08:42
User entered 'Day 2'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-22T18:40:15', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'b3228485-4d09-4347-9cd7-a6f99b85e7e7'	System	22 Aug 2020 22:40:37
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	22 Aug 2020 22:40:37

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-22T18:40:17', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'b3228485-4d09-4347-9cd7-a6f99b85e7e7'	System	22 Aug 2020 22:40:37
User entered 'No (N)'	System	22 Aug 2020 22:40:37

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-22T18:40:25', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'b3228485-4d09-4347-9cd7-a6f99b85e7e7'	System	22 Aug 2020 22:40:37
User entered 'No (N)'	System	22 Aug 2020 22:40:37

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-22T18:40:30', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'b3228485-4d09-4347-9cd7-a6f99b85e7e7'	System	22 Aug 2020 22:40:37
User entered 'None (1)'	System	22 Aug 2020 22:40:37

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-22T18:40:32', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'b3228485-4d09-4347-9cd7-a6f99b85e7e7' User entered '22 Aug 2020 18:40'	System	22 Aug 2020 22:40:37
	System	22 Aug 2020 22:40:37

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
Data entry locked.	System	21 Aug 2020 17:08:42
User entered 'Day 3'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T10:48:31', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '04b44373-dc3d-4555-b43c-bbd54522239b'	System	24 Aug 2020 14:48:41
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	24 Aug 2020 14:48:41

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T10:48:32', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '04b44373-dc3d-4555-b43c-bbd54522239b' User entered 'No (N)'	System	24 Aug 2020 14:48:41
	System	24 Aug 2020 14:48:41

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T10:48:35', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '04b44373-dc3d-4555-b43c-bbd54522239b' User entered 'No (N)'	System	24 Aug 2020 14:48:41
	System	24 Aug 2020 14:48:41

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T10:48:37', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '04b44373-dc3d-4555-b43c-bbd54522239b' User entered 'None (1)'	System	24 Aug 2020 14:48:41

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T10:48:39', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '04b44373-dc3d-4555-b43c-bbd54522239b' User entered '24 Aug 2020 10:48'	System	24 Aug 2020 14:48:41
	System	24 Aug 2020 14:48:41

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
Data entry locked.	System	21 Aug 2020 17:08:42
User entered 'Day 4'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T22:38:08', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '3ff3e7bb-9821-40f2-a3ad-416e71c2c729'	System	25 Aug 2020 02:38:18
User entered 'Does not interfere with activity (2)'	System	25 Aug 2020 02:38:18

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T22:38:10', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '3ff3e7bb-9821-40f2-a3ad-416e71c2c729' User entered 'No (N)'	System	25 Aug 2020 02:38:18
	System	25 Aug 2020 02:38:18

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T22:38:11', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '3ff3e7bb-9821-40f2-a3ad-416e71c2c729'	System	25 Aug 2020 02:38:18
User entered 'No (N)'	System	25 Aug 2020 02:38:18

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T22:38:13', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '3ff3e7bb-9821-40f2-a3ad-416e71c2c729'	System	25 Aug 2020 02:38:18
User entered 'None (1)'	System	25 Aug 2020 02:38:18

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T22:38:15', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '3ff3e7bb-9821-40f2-a3ad-416e71c2c729' User entered '24 Aug 2020 22:38'	System	25 Aug 2020 02:38:18
	System	25 Aug 2020 02:38:18

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
Data entry locked.	System	21 Aug 2020 17:08:42
User entered 'Day 5'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-25T22:43:31', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '7253ed26-1108-4411-a22d-a5733987548b' User entered 'None (1)'	System	26 Aug 2020 02:43:42
	System	26 Aug 2020 02:43:42

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-25T22:43:33', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '7253ed26-1108-4411-a22d-a5733987548b' User entered 'No (N)'	System	26 Aug 2020 02:43:42
	System	26 Aug 2020 02:43:42

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-25T22:43:35', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '7253ed26-1108-4411-a22d-a5733987548b' User entered 'No (N)'	System	26 Aug 2020 02:43:42
	System	26 Aug 2020 02:43:42

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-25T22:43:37', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '7253ed26-1108-4411-a22d-a5733987548b' User entered 'None (1)'	System	26 Aug 2020 02:43:42
	System	26 Aug 2020 02:43:42

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-25T22:43:39', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '7253ed26-1108-4411-a22d-a5733987548b' User entered '25 Aug 2020 22:43'	System	26 Aug 2020 02:43:42
	System	26 Aug 2020 02:43:42

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
Data entry locked.	System	21 Aug 2020 17:08:42
User entered 'Day 6'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T07:55:41', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '826cbc0c-ec93-4e5c-9acc-a54e474c2398'	System	27 Aug 2020 11:55:53
User entered 'None (1)'	System	27 Aug 2020 11:55:53

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T07:55:42', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '826cbc0c-ec93-4e5c-9acc-a54e474c2398'	System	27 Aug 2020 11:55:53
User entered 'No (N)'	System	27 Aug 2020 11:55:53

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T07:55:48', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '826cbc0c-ec93-4e5c-9acc-a54e474c2398'	System	27 Aug 2020 11:55:53
User entered 'No (N)'	System	27 Aug 2020 11:55:53

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T07:55:49', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '826cbc0c-ec93-4e5c-9acc-a54e474c2398' User entered 'None (1)'	System	27 Aug 2020 11:55:53
	System	27 Aug 2020 11:55:53

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T07:55:51', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '826cbc0c-ec93-4e5c-9acc-a54e474c2398' User entered '27 Aug 2020 07:55'	System	27 Aug 2020 11:55:53
	System	27 Aug 2020 11:55:53

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
Data entry locked.	System	21 Aug 2020 17:08:42
User entered 'Day 7'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T23:59:44', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a56bb5b6-12d7-41ee-8c5e-2eed2f1a63cb' User entered 'None (1)'	System	28 Aug 2020 03:59:55
	System	28 Aug 2020 03:59:55

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T23:59:46', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a56bb5b6-12d7-41ee-8c5e-2eed2f1a63cb'	System	28 Aug 2020 03:59:55
User entered 'No (N)'	System	28 Aug 2020 03:59:55

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T23:59:49', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a56bb5b6-12d7-41ee-8c5e-2eed2f1a63cb' User entered 'No (N)'	System	28 Aug 2020 03:59:55
	System	28 Aug 2020 03:59:55

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T23:59:52', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a56bb5b6-12d7-41ee-8c5e-2eed2f1a63cb' User entered 'None (1)'	System	28 Aug 2020 03:59:55
	System	28 Aug 2020 03:59:55

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T23:59:54', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a56bb5b6-12d7-41ee-8c5e-2eed2f1a63cb' User entered '27 Aug 2020 23:59'	System	28 Aug 2020 03:59:55
	System	28 Aug 2020 03:59:55

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
Data entry locked.	System	21 Aug 2020 17:08:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T13:34:16', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ad492cd9-ac87-4bce-9a64-c3282a4c21d3'	System	21 Aug 2020 17:34:54
User entered 'No interference with activity (1)'	System	21 Aug 2020 17:34:54

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T13:34:21', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ad492cd9-ac87-4bce-9a64-c3282a4c21d3' User entered 'None (0)'	System	21 Aug 2020 17:34:54
	System	21 Aug 2020 17:34:54

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T13:34:24', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ad492cd9-ac87-4bce-9a64-c3282a4c21d3'	System	21 Aug 2020 17:34:54
User entered 'No interference with activity (1)'	System	21 Aug 2020 17:34:54

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T13:34:28', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ad492cd9-ac87-4bce-9a64-c3282a4c21d3' User entered 'None (0)'	System	21 Aug 2020 17:34:54
	System	21 Aug 2020 17:34:54

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T13:34:33', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ad492cd9-ac87-4bce-9a64-c3282a4c21d3' User entered 'None (0)'	System	21 Aug 2020 17:34:54
	System	21 Aug 2020 17:34:54

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T13:34:37', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ad492cd9-ac87-4bce-9a64-c3282a4c21d3' User entered 'None (0)'	System	21 Aug 2020 17:34:54
	System	21 Aug 2020 17:34:54

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T13:34:48', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ad492cd9-ac87-4bce-9a64-c3282a4c21d3' User entered 'No (N)'	System	21 Aug 2020 17:34:54
	System	21 Aug 2020 17:34:54

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T13:34:50', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ad492cd9-ac87-4bce-9a64-c3282a4c21d3' User entered '21 Aug 2020 13:34'	System	21 Aug 2020 17:34:54
	System	21 Aug 2020 17:34:54

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '21 Aug 2020 13:16'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '21 Aug 2020 15:46'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
Data entry locked.	System	21 Aug 2020 17:08:42
User entered 'Day 1, after vaccination (at home)'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T16:50:29', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bffc2fa9-1c65-4224-94df-3eebde7983a2'	System	21 Aug 2020 20:51:04
User entered 'No interference with activity (1)'	System	21 Aug 2020 20:51:04

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T16:50:33', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bffc2fa9-1c65-4224-94df-3eebde7983a2'	System	21 Aug 2020 20:51:04
User entered 'Some interference with activity (2)'	System	21 Aug 2020 20:51:04

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T16:50:43', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bffc2fa9-1c65-4224-94df-3eebde7983a2'	System	21 Aug 2020 20:51:04
User entered 'No interference with activity (1)'	System	21 Aug 2020 20:51:04

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T16:50:45', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bffc2fa9-1c65-4224-94df-3eebde7983a2' User entered 'None (0)'	System	21 Aug 2020 20:51:04
	System	21 Aug 2020 20:51:04

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T16:50:49', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bffc2fa9-1c65-4224-94df-3eebde7983a2'	System	21 Aug 2020 20:51:04
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	21 Aug 2020 20:51:04

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T16:50:54', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bffc2fa9-1c65-4224-94df-3eebde7983a2'	System	21 Aug 2020 20:51:04
User entered 'Some interference with activity not requiring medical attention (2)'	System	21 Aug 2020 20:51:04

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T16:50:59', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bffc2fa9-1c65-4224-94df-3eebde7983a2'	System	21 Aug 2020 20:51:04
User entered 'No (N)'	System	21 Aug 2020 20:51:04

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-21T16:51:02', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bffc2fa9-1c65-4224-94df-3eebde7983a2'	System	21 Aug 2020 20:51:04
User entered '21 Aug 2020 16:51'	System	21 Aug 2020 20:51:04

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '21 Aug 2020 16:41'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '22 Aug 2020 11:59'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
Data entry locked.	System	21 Aug 2020 17:08:42
User entered 'Day 2'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-22T18:40:37', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6d37dd8f-2825-4e9b-bda9-3766c5c328d0' User entered 'None (0)'	System	22 Aug 2020 22:41:08
	System	22 Aug 2020 22:41:08

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-22T18:40:41', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6d37dd8f-2825-4e9b-bda9-3766c5c328d0'	System	22 Aug 2020 22:41:08
User entered 'Some interference with activity (2)'	System	22 Aug 2020 22:41:08

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-22T18:40:46', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6d37dd8f-2825-4e9b-bda9-3766c5c328d0'	System	22 Aug 2020 22:41:08
User entered 'Some interference with activity (2)'	System	22 Aug 2020 22:41:08

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-22T18:40:48', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6d37dd8f-2825-4e9b-bda9-3766c5c328d0' User entered 'None (0)'	System	22 Aug 2020 22:41:08
	System	22 Aug 2020 22:41:08

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-22T18:40:57', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6d37dd8f-2825-4e9b-bda9-3766c5c328d0'	System	22 Aug 2020 22:41:08
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	22 Aug 2020 22:41:08

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-22T18:40:59', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6d37dd8f-2825-4e9b-bda9-3766c5c328d0' User entered 'None (0)'	System	22 Aug 2020 22:41:08
	System	22 Aug 2020 22:41:08

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-22T18:41:03', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6d37dd8f-2825-4e9b-bda9-3766c5c328d0' User entered 'No (N)'	System	22 Aug 2020 22:41:08
	System	22 Aug 2020 22:41:08

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-22T18:41:06', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6d37dd8f-2825-4e9b-bda9-3766c5c328d0' User entered '22 Aug 2020 18:41'	System	22 Aug 2020 22:41:08
	System	22 Aug 2020 22:41:08

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '22 Aug 2020 12:00'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '23 Aug 2020 11:59'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
Data entry locked.	System	21 Aug 2020 17:08:42
User entered 'Day 3'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T10:48:45', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'd8a4ab04-b861-46fb-a081-bf1869ecd90d'	System	24 Aug 2020 14:49:08
User entered 'No interference with activity (1)'	System	24 Aug 2020 14:49:08

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T10:48:49', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'd8a4ab04-b861-46fb-a081-bf1869ecd90d'	System	24 Aug 2020 14:49:08
User entered 'Some interference with activity (2)'	System	24 Aug 2020 14:49:08

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T10:48:53', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'd8a4ab04-b861-46fb-a081-bf1869ecd90d' User entered 'None (0)'	System	24 Aug 2020 14:49:08
	System	24 Aug 2020 14:49:08

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T10:48:54', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'd8a4ab04-b861-46fb-a081-bf1869ecd90d' User entered 'None (0)'	System	24 Aug 2020 14:49:08
	System	24 Aug 2020 14:49:08

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T10:48:57', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'd8a4ab04-b861-46fb-a081-bf1869ecd90d'	System	24 Aug 2020 14:49:08
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	24 Aug 2020 14:49:08

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T10:48:59', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'd8a4ab04-b861-46fb-a081-bf1869ecd90d' User entered 'None (0)'	System	24 Aug 2020 14:49:08
	System	24 Aug 2020 14:49:08

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T10:49:01', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'd8a4ab04-b861-46fb-a081-bf1869ecd90d' User entered 'No (N)'	System	24 Aug 2020 14:49:08
	System	24 Aug 2020 14:49:08

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T10:49:03', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'd8a4ab04-b861-46fb-a081-bf1869ecd90d' User entered '24 Aug 2020 10:49'	System	24 Aug 2020 14:49:08
	System	24 Aug 2020 14:49:08

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '23 Aug 2020 12:00'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '24 Aug 2020 11:59'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
Data entry locked.	System	21 Aug 2020 17:08:42
User entered 'Day 4'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T22:38:18', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'c941931e-dada-4db2-aef3-a03ceb2a6548' User entered 'None (0)'	System	25 Aug 2020 02:38:45
	System	25 Aug 2020 02:38:45

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T22:38:41', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'c941931e-dada-4db2-aef3-a03ceb2a6548'	System	25 Aug 2020 02:38:45
User entered 'Some interference with activity (2)'	System	25 Aug 2020 02:38:45

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T22:38:23', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'c941931e-dada-4db2-aef3-a03ceb2a6548' User entered 'None (0)'	System	25 Aug 2020 02:38:45
	System	25 Aug 2020 02:38:45

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T22:38:25', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'c941931e-dada-4db2-aef3-a03ceb2a6548' User entered 'None (0)'	System	25 Aug 2020 02:38:45
	System	25 Aug 2020 02:38:45

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T22:38:32', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'c941931e-dada-4db2-aef3-a03ceb2a6548'	System	25 Aug 2020 02:38:45
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	25 Aug 2020 02:38:45

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T22:38:34', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'c941931e-dada-4db2-aef3-a03ceb2a6548' User entered 'None (0)'	System	25 Aug 2020 02:38:45
	System	25 Aug 2020 02:38:45

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T22:38:35', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'c941931e-dada-4db2-aef3-a03ceb2a6548' User entered 'No (N)'	System	25 Aug 2020 02:38:45
	System	25 Aug 2020 02:38:45

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-24T22:38:42', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'c941931e-dada-4db2-aef3-a03ceb2a6548' User entered '24 Aug 2020 22:38'	System	25 Aug 2020 02:38:45
	System	25 Aug 2020 02:38:45

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '24 Aug 2020 12:00'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '25 Aug 2020 11:59'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
Data entry locked.	System	21 Aug 2020 17:08:42
User entered 'Day 5'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-25T22:43:43', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '85142b5e-c51f-48aa-b5cb-5f0726ad0d7e' User entered 'None (0)'	System	26 Aug 2020 02:44:04
	System	26 Aug 2020 02:44:04

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-25T22:43:45', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '85142b5e-c51f-48aa-b5cb-5f0726ad0d7e' User entered 'None (0)'	System	26 Aug 2020 02:44:04
	System	26 Aug 2020 02:44:04

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-25T22:43:47', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '85142b5e-c51f-48aa-b5cb-5f0726ad0d7e' User entered 'None (0)'	System	26 Aug 2020 02:44:04
	System	26 Aug 2020 02:44:04

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-25T22:43:48', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '85142b5e-c51f-48aa-b5cb-5f0726ad0d7e' User entered 'None (0)'	System	26 Aug 2020 02:44:04
	System	26 Aug 2020 02:44:04

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-25T22:43:51', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '85142b5e-c51f-48aa-b5cb-5f0726ad0d7e' User entered 'None (0)'	System	26 Aug 2020 02:44:04
	System	26 Aug 2020 02:44:04

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-25T22:43:54', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '85142b5e-c51f-48aa-b5cb-5f0726ad0d7e' User entered 'None (0)'	System	26 Aug 2020 02:44:04
	System	26 Aug 2020 02:44:04

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-25T22:43:59', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '85142b5e-c51f-48aa-b5cb-5f0726ad0d7e' User entered 'No (N)'	System	26 Aug 2020 02:44:04
	System	26 Aug 2020 02:44:04

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-25T22:44:01', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '85142b5e-c51f-48aa-b5cb-5f0726ad0d7e' User entered '25 Aug 2020 22:44'	System	26 Aug 2020 02:44:04
	System	26 Aug 2020 02:44:04

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '25 Aug 2020 12:00'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '26 Aug 2020 11:59'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
Data entry locked.	System	21 Aug 2020 17:08:42
User entered 'Day 6'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T07:56:01', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6e271199-a493-4234-ae18-adbd9f349279'	System	27 Aug 2020 11:56:20
User entered 'Any use of prescription pain reliever or System prevents daily activity (3)'		27 Aug 2020 11:56:20

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T07:56:04', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6e271199-a493-4234-ae18-adbd9f349279' User entered 'None (0)'	System	27 Aug 2020 11:56:20
	System	27 Aug 2020 11:56:20

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T07:56:05', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6e271199-a493-4234-ae18-adbd9f349279' User entered 'None (0)'	System	27 Aug 2020 11:56:20
	System	27 Aug 2020 11:56:20

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T07:56:06', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6e271199-a493-4234-ae18-adbd9f349279' User entered 'None (0)'	System	27 Aug 2020 11:56:20
	System	27 Aug 2020 11:56:20

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T07:56:12', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6e271199-a493-4234-ae18-adbd9f349279'	System	27 Aug 2020 11:56:20
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	27 Aug 2020 11:56:20

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T07:56:13', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6e271199-a493-4234-ae18-adbd9f349279' User entered 'None (0)'	System	27 Aug 2020 11:56:20
	System	27 Aug 2020 11:56:20

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T07:56:16', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6e271199-a493-4234-ae18-adbd9f349279' User entered 'No (N)'	System	27 Aug 2020 11:56:20
	System	27 Aug 2020 11:56:20

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T07:56:17', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6e271199-a493-4234-ae18-adbd9f349279' User entered '27 Aug 2020 07:56'	System	27 Aug 2020 11:56:20
	System	27 Aug 2020 11:56:20

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '26 Aug 2020 12:00'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '27 Aug 2020 11:59'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
Data entry locked.	System	21 Aug 2020 17:08:42
User entered 'Day 7'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-27T23:59:58', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a99d6e2c-e36e-4bd4-adff-0020bc4d2ac1' User entered 'None (0)'	System	28 Aug 2020 04:00:26
	System	28 Aug 2020 04:00:26

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-28T00:00:00', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a99d6e2c-e36e-4bd4-adff-0020bc4d2ac1' User entered 'None (0)'	System	28 Aug 2020 04:00:26
	System	28 Aug 2020 04:00:26

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-28T00:00:01', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a99d6e2c-e36e-4bd4-adff-0020bc4d2ac1' User entered 'None (0)'	System	28 Aug 2020 04:00:26
	System	28 Aug 2020 04:00:26

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-28T00:00:06', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a99d6e2c-e36e-4bd4-adff-0020bc4d2ac1' User entered 'None (0)'	System	28 Aug 2020 04:00:26
	System	28 Aug 2020 04:00:26

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-28T00:00:07', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a99d6e2c-e36e-4bd4-adff-0020bc4d2ac1' User entered 'None (0)'	System	28 Aug 2020 04:00:26
	System	28 Aug 2020 04:00:26

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-28T00:00:09', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a99d6e2c-e36e-4bd4-adff-0020bc4d2ac1' User entered 'None (0)'	System	28 Aug 2020 04:00:26
	System	28 Aug 2020 04:00:26

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-28T00:00:11', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a99d6e2c-e36e-4bd4-adff-0020bc4d2ac1' User entered 'No (N)'	System	28 Aug 2020 04:00:26
	System	28 Aug 2020 04:00:26

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-08-28T00:00:14', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a99d6e2c-e36e-4bd4-adff-0020bc4d2ac1' User entered '28 Aug 2020 00:00'	System	28 Aug 2020 04:00:26
	System	28 Aug 2020 04:00:26

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '27 Aug 2020 12:00'	System	21 Aug 2020 17:08:42

US3432229

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:29:41
User entered '28 Aug 2020 11:59'	System	21 Aug 2020 17:08:42

US3432229

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	29 Aug 2020 17:22:51

US3432229

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '29 Aug 2020'	Julia Klopfer (b) (4)	29 Aug 2020 17:22:51

US3432229

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Contact Made (CONTACT MADE)'	Julia Klopfer (b) (4)	29 Aug 2020 17:22:51

US3432229

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty.	Julia Klopfer (b) (4)	29 Aug 2020 17:22:51

US3432229

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	29 Aug 2020 17:22:56

US3432229

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'I'	System	29 Aug 2020 17:22:56

US3432229

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:01:44

US3432229

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '05 Sep 2020' reason for change: Per Query Resolution	Xhoi Mitre (b) (4)	10 Nov 2020 15:10:19
User entered '5 Sep 2020'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:01:44

US3432229

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:01:44

US3432229

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Phoebe Cunningham (b) (4)	05 Sep 2020 14:01:44

US3432229

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:03:36

US3432229

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'I'	System	05 Sep 2020 14:03:36

US3432229

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 15:01:15

US3432229

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '11 Sep 2020'	(b) (4), (b) (6)	11 Sep 2020 15:01:15

US3432229

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Sep 2020 15:01:15

US3432229

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	(b) (4), (b) (6)	11 Sep 2020 15:01:15

US3432229

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Sep 2020 15:02:43

US3432229

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'I'	System	11 Sep 2020 15:02:43

US3432229

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User closed query 'Per GCL Lab Recon: it appears GCL has a Swab Sample with date 18SEP2020 for Visit 2 Day29 ; however there is no record in EDC. Please reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 12:47:14
Query 'Per GCL Lab Recon: it appears GCL has a Swab Sample with date 18SEP2020 for Visit 2 Day29 ; however there is no record in EDC. Please reconcile or clarify' answered with 'yes it was done' (Site from DM).	Monica Feeley (b) (4)	10 Nov 2020 21:55:59
User opened query 'Per GCL Lab Recon: it appears GCL has a Swab Sample with date 18SEP2020 for Visit 2 Day29 ; however there is no record in EDC. Please reconcile or clarify' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 11:49:52
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	18 Sep 2020 16:15:27

US3432229

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:54

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 18SEP2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 09:46:56
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 18SEP2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'yes it was done' (Site from DM).	Monica Feeley (b) (4)	10 Nov 2020 21:56:03
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 18SEP2020 is reported under Visit 2 Day 29visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 05:51:41
User entered '18 Sep 2020'	Bruce Bausk (b) (4)	18 Sep 2020 16:15:27

US3432229

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:54

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Clinic (Clinic)'	Bruce Bausk (b) (4)	18 Sep 2020 16:15:27

US3432229

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'VISIT2'	System	18 Sep 2020 16:15:27

US3432229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User accepted default value 'Pre-Dose (PREDOSE)'	Bruce Bausk (b) (4) (b) (4)	18 Sep 2020 16:19:05

US3432229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	18 Sep 2020 16:19:05

US3432229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '18 Sep 2020'	Bruce Bausk (b) (4)	18 Sep 2020 16:19:05

US3432229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '10:47'	Bruce Bausk (b) (4)	18 Sep 2020 16:19:05

US3432229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered '18 Sep 2020 10:47'	System	18 Sep 2020 16:19:05

US3432229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '37.0' C	Bruce Bausk (b) (4)	18 Sep 2020 16:19:05

US3432229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Oral (Oral)'	Bruce Bausk (b) (4)	18 Sep 2020 16:19:05

US3432229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty.	Bruce Bausk (b) (4)	18 Sep 2020 16:19:05

US3432229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '74'	Bruce Bausk (b) (4)	18 Sep 2020 16:19:05

US3432229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'bpm'	System	18 Sep 2020 16:19:05

US3432229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '14'	Bruce Bausk (b) (4)	18 Sep 2020 16:19:05

US3432229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'breaths/min'	System	18 Sep 2020 16:19:05

US3432229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '113'	Bruce Bausk (b) (4)	18 Sep 2020 16:19:05

US3432229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'mmHg'	System	18 Sep 2020 16:19:05

US3432229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '68'	Bruce Bausk (b) (4)	18 Sep 2020 16:19:05

US3432229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:35:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'mmHg'	System	18 Sep 2020 16:19:05

US3432229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:54

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User accepted default value 'Post-Dose (POSTDOSE)'	Bruce Bausk (b) (4) (b) (4)	18 Sep 2020 16:19:05

US3432229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	18 Sep 2020 16:19:05

US3432229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '18 Sep 2020'	Bruce Bausk (b) (4)	18 Sep 2020 16:19:05

US3432229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '11:44'	Bruce Bausk (b) (4)	18 Sep 2020 16:19:05

US3432229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered '18 Sep 2020 11:44'	System	18 Sep 2020 16:19:05

US3432229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '36.5' C	Bruce Bausk (b) (4)	18 Sep 2020 16:19:05

US3432229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Other (Other)'	Bruce Bausk (b) (4)	18 Sep 2020 16:19:05

US3432229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'IR'	Bruce Bausk (b) (4)	18 Sep 2020 16:19:05

US3432229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '73'	Bruce Bausk (b) (4)	18 Sep 2020 16:19:05

US3432229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'bpm'	System	18 Sep 2020 16:19:05

US3432229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '14'	Bruce Bausk (b) (4)	18 Sep 2020 16:19:05

US3432229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'breaths/min'	System	18 Sep 2020 16:19:05

US3432229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '109'	Bruce Bausk (b) (4)	18 Sep 2020 16:19:05

US3432229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'mmHg'	System	18 Sep 2020 16:19:05

US3432229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '61'	Bruce Bausk (b) (4)	18 Sep 2020 16:19:05

US3432229

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:35:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'mmHg'	System	18 Sep 2020 16:19:05

US3432229

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:35:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	18 Sep 2020 16:20:57

US3432229

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:35:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '18 Sep 2020'	Bruce Bausk (b) (4)	18 Sep 2020 16:20:57

US3432229

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:35:54

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	18 Sep 2020 16:21:08

US3432229

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:35:54

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '18 Sep 2020'	Bruce Bausk (b) (4)	18 Sep 2020 16:21:08

US3432229

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:35:54

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Urine (URINE)'	Bruce Bausk (b) (4)	18 Sep 2020 16:21:08

US3432229

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:35:54

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Negative (NEGATIVE)'	Bruce Bausk (b) (4)	18 Sep 2020 16:21:08

US3432229

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:35:54

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'No (N)'	Bruce Bausk (b) (4)	18 Sep 2020 16:21:08

US3432229

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:35:54

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty.	Bruce Bausk (b) (4)	18 Sep 2020 16:21:08

US3432229

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:35:54

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty.	Bruce Bausk (b) (4)	18 Sep 2020 16:21:08

US3432229

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered empty.	System	18 Sep 2020 16:21:08

US3432229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:54

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
Query 'Per CDM: Please complete Immunogenicity and Central Lab forms. ' canceled (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 06:14:19
User opened query 'Per CDM: Please complete Immunogenicity and Central Lab forms. ' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 21:56:12
User entered 'Yes (Y)'	Bruce Bausk (b) (4)	18 Sep 2020 15:40:31

US3432229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:54

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty.	Bruce Bausk (b) (4)	18 Sep 2020 15:40:31

US3432229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty.	Bruce Bausk (b) (4)	18 Sep 2020 15:40:31

US3432229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:54

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'MRNA-1273 OR PLACEBO'	System	18 Sep 2020 15:40:31

US3432229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:54

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '18 Sep 2020'	Bruce Bausk (b) (4)	18 Sep 2020 15:40:31

US3432229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:54

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '11:14'	Bruce Bausk (b) (4)	18 Sep 2020 15:40:31

US3432229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:54

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered '18 Sep 2020 11:14'	System	18 Sep 2020 15:40:31

US3432229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:54

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Left Arm (LEFT ARM)'	Bruce Bausk (b) (4)	18 Sep 2020 15:40:31

US3432229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:54

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'ONCE'	System	18 Sep 2020 15:40:31

US3432229

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:35:54

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'INTRAMUSCULAR'	System	18 Sep 2020 15:40:31

US3432229

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Yes (Y)'	Monica Feeley (b) (4)	10 Nov 2020 21:56:28

US3432229

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:54

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '18 Sep 2020'	Monica Feeley (b) (4)	10 Nov 2020 21:56:28

US3432229

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:54

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '11:00'	Monica Feeley (b) (4)	10 Nov 2020 21:56:28

US3432229

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered '18 Sep 2020 11:00'	System	10 Nov 2020 21:56:28

US3432229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:35:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '18 Sep 2020'	Monica Feeley (b) (4)	10 Nov 2020 21:56:42

US3432229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:35:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 21:56:42

US3432229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:35:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Yes (Y)'	Monica Feeley (b) (4)	10 Nov 2020 21:56:42

US3432229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:35:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '11:05'	Monica Feeley (b) (4)	10 Nov 2020 21:56:42

US3432229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered '18 Sep 2020 11:05'	System	10 Nov 2020 21:56:42

US3432229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:35:54

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Monica Feeley (b) (4) (b) (4)	10 Nov 2020 21:56:42

US3432229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:35:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'No (N)'	Monica Feeley (b) (4)	10 Nov 2020 21:56:42

US3432229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:35:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty.	Monica Feeley (b) (4)	10 Nov 2020 21:56:42

US3432229

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered empty.	System	10 Nov 2020 21:56:42

US3432229

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 14:40:30

US3432229

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'I'	System	25 Sep 2020 14:40:30

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
Data entry locked.	System	18 Sep 2020 15:40:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T11:45:35', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '5ebf483a-0036-4051-960e-aa3864f19148' User entered 'Yes (Y)'	System	18 Sep 2020 15:45:49
	System	18 Sep 2020 15:45:49

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T11:45:41', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '5ebf483a-0036-4051-960e-aa3864f19148' User entered '97.7'	System	18 Sep 2020 15:45:49
	System	18 Sep 2020 15:45:49

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T11:45:44', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '5ebf483a-0036-4051-960e-aa3864f19148' User entered 'No (N)'	System	18 Sep 2020 15:45:49
	System	18 Sep 2020 15:45:49

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T11:45:46', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '5ebf483a-0036-4051-960e-aa3864f19148' User entered '18 Sep 2020 11:45'	System	18 Sep 2020 15:45:49
	System	18 Sep 2020 15:45:49

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '18 Sep 2020 11:34'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '18 Sep 2020 14:04'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
Data entry locked.	System	18 Sep 2020 15:40:31
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T20:50:25', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '19fc3b27-8f0f-4482-88b5-3b12a134e582'	System	19 Sep 2020 00:50:38
User entered 'Yes (Y)'	System	19 Sep 2020 00:50:38

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T20:50:30', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '19fc3b27-8f0f-4482-88b5-3b12a134e582' User entered '98.3'	System	19 Sep 2020 00:50:38
	System	19 Sep 2020 00:50:38

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T20:50:32', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '19fc3b27-8f0f-4482-88b5-3b12a134e582'	System	19 Sep 2020 00:50:38
User entered 'No (N)'	System	19 Sep 2020 00:50:38

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T20:50:35', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '19fc3b27-8f0f-4482-88b5-3b12a134e582'	System	19 Sep 2020 00:50:38
User entered '18 Sep 2020 20:50'	System	19 Sep 2020 00:50:38

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '18 Sep 2020 14:59'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
Data entry locked.	System	18 Sep 2020 15:40:31
User entered 'Day 2'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-19T12:54:16', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '5f65ad10-96a5-41bd-abbf-0966b3a12612' User entered 'Yes (Y)'	System	19 Sep 2020 16:54:29
	System	19 Sep 2020 16:54:29

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-19T12:54:20', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '5f65ad10-96a5-41bd-abbf-0966b3a12612' User entered '99.3'	System	19 Sep 2020 16:54:29
	System	19 Sep 2020 16:54:29

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-19T12:54:23', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '5f65ad10-96a5-41bd-abbf-0966b3a12612'	System	19 Sep 2020 16:54:29
User entered 'Yes (Y)'	System	19 Sep 2020 16:54:29

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
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 'participant contacted and ibuprofen and tylenol added to conmedications' (Site from System).	(b) (4), (b) (6)	30 Sep 2020 16:46:11
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-19T12:54:26', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '5f65ad10-96a5-41bd-abbf-0966b3a12612' User entered '1'	Phoebe Cunningham (b) (4)	25 Sep 2020 21:17:38
	System	19 Sep 2020 16:54:29
	System	19 Sep 2020 16:54:29
	System	19 Sep 2020 16:54:29

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:54

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-19T12:54:26', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '5f65ad10-96a5-41bd-abbf-0966b3a12612'	System	19 Sep 2020 16:54:29
User entered '0'	System	19 Sep 2020 16:54:29

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-19T12:54:28', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '5f65ad10-96a5-41bd-abbf-0966b3a12612' User entered '19 Sep 2020 12:54'	System	19 Sep 2020 16:54:29
	System	19 Sep 2020 16:54:29

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
Data entry locked.	System	18 Sep 2020 15:40:31
User entered 'Day 3'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-20T17:07:08', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '3134c093-052c-42a5-8670-89208c5d4102'	System	20 Sep 2020 21:07:46
User entered 'Yes (Y)'	System	20 Sep 2020 21:07:46

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-20T17:07:35', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '3134c093-052c-42a5-8670-89208c5d4102'	System	20 Sep 2020 21:07:46
User entered '97.0'	System	20 Sep 2020 21:07:46

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-20T17:07:38', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '3134c093-052c-42a5-8670-89208c5d4102'	System	20 Sep 2020 21:07:46
User entered 'Yes (Y)'	System	20 Sep 2020 21:07:46

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
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 'participant contacted and ibuprofen and tylenol added to conmedications' (Site from System).	(b) (4), (b) (6)	30 Sep 2020 16:46:15
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-20T17:07:41', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '3134c093-052c-42a5-8670-89208c5d4102'	Phoebe Cunningham (b) (4)	25 Sep 2020 21:17:45
User entered '1'	System	20 Sep 2020 21:07:46
	System	20 Sep 2020 21:07:46
	System	20 Sep 2020 21:07:46

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:54

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User closed query 'Per the participant response, medication was taken to prevent 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 prevent 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 'participant contacted and ibuprofen and tylenol added to conmedications' (Site from System).	(b) (4), (b) (6)	30 Sep 2020 16:46:17
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-20T17:07:41', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '3134c093-052c-42a5-8670-89208c5d4102'	Phoebe Cunningham (b) (4)	25 Sep 2020 21:17:49
User entered '1'	System	20 Sep 2020 21:07:46
	System	20 Sep 2020 21:07:46
	System	20 Sep 2020 21:07:46

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-20T17:07:43', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '3134c093-052c-42a5-8670-89208c5d4102'	System	20 Sep 2020 21:07:46
User entered '20 Sep 2020 17:07'	System	20 Sep 2020 21:07:46

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
Data entry locked.	System	18 Sep 2020 15:40:31
User entered 'Day 4'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-22T00:00:15', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '7997dcfa-7756-495f-b994-f44e9e56f7f8'	System	22 Sep 2020 04:00:28
User entered 'Yes (Y)'	System	22 Sep 2020 04:00:28

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-22T00:00:21', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '7997dcfa-7756-495f-b994-f44e9e56f7f8'	System	22 Sep 2020 04:00:28
User entered '97.0'	System	22 Sep 2020 04:00:28

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-22T00:00:24', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '7997dcfa-7756-495f-b994-f44e9e56f7f8'	System	22 Sep 2020 04:00:28
User entered 'No (N)'	System	22 Sep 2020 04:00:28

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-22T00:00:26', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '7997dcfa-7756-495f-b994-f44e9e56f7f8' User entered '22 Sep 2020 00:00'	System	22 Sep 2020 04:00:28
	System	22 Sep 2020 04:00:28

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
Data entry locked.	System	18 Sep 2020 15:40:31
User entered 'Day 5'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T02:55:09', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'da75f623-e940-4e2f-ad95-d26d1e02f4c0'	System	23 Sep 2020 06:55:29
User entered 'Yes (Y)'	System	23 Sep 2020 06:55:29

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T02:55:20', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'da75f623-e940-4e2f-ad95-d26d1e02f4c0' User entered '97.0'	System	23 Sep 2020 06:55:29
	System	23 Sep 2020 06:55:29

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T02:55:23', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'da75f623-e940-4e2f-ad95-d26d1e02f4c0'	System	23 Sep 2020 06:55:29
User entered 'No (N)'	System	23 Sep 2020 06:55:29

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T02:55:26', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'da75f623-e940-4e2f-ad95-d26d1e02f4c0' User entered '23 Sep 2020 02:55'	System	23 Sep 2020 06:55:29
	System	23 Sep 2020 06:55:29

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
Data entry locked.	System	18 Sep 2020 15:40:31
User entered 'Day 6'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T21:41:20', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a34f9f5c-5e50-4ece-a062-f0480244d6a3' User entered 'Yes (Y)'	System	24 Sep 2020 01:41:37
	System	24 Sep 2020 01:41:37

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T21:41:24', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a34f9f5c-5e50-4ece-a062-f0480244d6a3' User entered '98.2'	System	24 Sep 2020 01:41:37
	System	24 Sep 2020 01:41:37

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T21:41:27', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a34f9f5c-5e50-4ece-a062-f0480244d6a3'	System	24 Sep 2020 01:41:37
User entered 'Yes (Y)'	System	24 Sep 2020 01:41:37

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
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 'participant contacted and ibuprofen and tylenol added to conmedications' (Site from System).	(b) (4), (b) (6)	30 Sep 2020 16:46:26
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T21:41:30', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a34f9f5c-5e50-4ece-a062-f0480244d6a3' User entered '1'	Phoebe Cunningham (b) (4)	25 Sep 2020 21:18:06
	System	24 Sep 2020 01:41:37
	System	24 Sep 2020 01:41:37
	System	24 Sep 2020 01:41:37

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:54

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T21:41:30', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a34f9f5c-5e50-4ece-a062-f0480244d6a3' User entered '0'	System	24 Sep 2020 01:41:37
	System	24 Sep 2020 01:41:37

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T21:41:33', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a34f9f5c-5e50-4ece-a062-f0480244d6a3' User entered '23 Sep 2020 21:41'	System	24 Sep 2020 01:41:37
	System	24 Sep 2020 01:41:37

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
Data entry locked.	System	18 Sep 2020 15:40:31
User entered 'Day 7'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:54

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-24T23:59:16', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6eb92e0a-ebb8-441c-b606-6d2f94069bda' User entered 'Yes (Y)'	System	25 Sep 2020 03:59:32
	System	25 Sep 2020 03:59:32

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:54

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-24T23:59:20', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6eb92e0a-ebb8-441c-b606-6d2f94069bda' User entered '98.3'	System	25 Sep 2020 03:59:32
	System	25 Sep 2020 03:59:32

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-24T23:59:24', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6eb92e0a-ebb8-441c-b606-6d2f94069bda' User entered 'No (N)'	System	25 Sep 2020 03:59:32
	System	25 Sep 2020 03:59:32

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-24T23:59:26', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6eb92e0a-ebb8-441c-b606-6d2f94069bda' User entered '24 Sep 2020 23:59'	System	25 Sep 2020 03:59:32
	System	25 Sep 2020 03:59:32

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
Data entry locked.	System	18 Sep 2020 15:40:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T11:45:52', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '424d9ee4-c7cf-4cb6-80cf-9b37d4b7c8d6'	System	18 Sep 2020 15:46:21
User entered 'Does not interfere with activity (2)'	System	18 Sep 2020 15:46:21

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T11:46:08', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '424d9ee4-c7cf-4cb6-80cf-9b37d4b7c8d6'	System	18 Sep 2020 15:46:21
User entered 'No (N)'	System	18 Sep 2020 15:46:21

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T11:46:10', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '424d9ee4-c7cf-4cb6-80cf-9b37d4b7c8d6'	System	18 Sep 2020 15:46:21
User entered 'No (N)'	System	18 Sep 2020 15:46:21

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T11:46:16', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '424d9ee4-c7cf-4cb6-80cf-9b37d4b7c8d6'	System	18 Sep 2020 15:46:21
User entered 'None (1)'	System	18 Sep 2020 15:46:21

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T11:46:18', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '424d9ee4-c7cf-4cb6-80cf-9b37d4b7c8d6'	System	18 Sep 2020 15:46:21
User entered '18 Sep 2020 11:46'	System	18 Sep 2020 15:46:21

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '18 Sep 2020 11:34'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '18 Sep 2020 14:04'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
Data entry locked.	System	18 Sep 2020 15:40:31
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T20:50:42', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'cdf8bcc9-99e4-4046-821d-713131af28fb'	System	19 Sep 2020 00:50:55
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	19 Sep 2020 00:50:55

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T20:50:45', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'cdf8bcc9-99e4-4046-821d-713131af28fb' User entered 'No (N)'	System	19 Sep 2020 00:50:55
	System	19 Sep 2020 00:50:55

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T20:50:47', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'cdf8bcc9-99e4-4046-821d-713131af28fb' User entered 'No (N)'	System	19 Sep 2020 00:50:55
	System	19 Sep 2020 00:50:55

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T20:50:50', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'cdf8bcc9-99e4-4046-821d-713131af28fb' User entered 'None (1)'	System	19 Sep 2020 00:50:55
	System	19 Sep 2020 00:50:55

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T20:50:53', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'cdf8bcc9-99e4-4046-821d-713131af28fb' User entered '18 Sep 2020 20:50'	System	19 Sep 2020 00:50:55
	System	19 Sep 2020 00:50:55

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '18 Sep 2020 14:59'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
Data entry locked.	System	18 Sep 2020 15:40:31
User entered 'Day 2'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-19T12:54:37', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '480c77aa-3110-4ec2-923a-102bf5d3265b'	System	19 Sep 2020 16:54:49
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	19 Sep 2020 16:54:49

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-19T12:54:41', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '480c77aa-3110-4ec2-923a-102bf5d3265b' User entered 'No (N)'	System	19 Sep 2020 16:54:49
	System	19 Sep 2020 16:54:49

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-19T12:54:43', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '480c77aa-3110-4ec2-923a-102bf5d3265b' User entered 'No (N)'	System	19 Sep 2020 16:54:49
	System	19 Sep 2020 16:54:49

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-19T12:54:45', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '480c77aa-3110-4ec2-923a-102bf5d3265b' User entered 'None (1)'	System	19 Sep 2020 16:54:49
	System	19 Sep 2020 16:54:49

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-19T12:54:46', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '480c77aa-3110-4ec2-923a-102bf5d3265b' User entered '19 Sep 2020 12:54'	System	19 Sep 2020 16:54:49
	System	19 Sep 2020 16:54:49

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
Data entry locked.	System	18 Sep 2020 15:40:31
User entered 'Day 3'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-20T17:03:50', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'aa038c48-491c-409e-a7d7-3ddef7818b3c'	System	20 Sep 2020 21:04:04
User entered 'Does not interfere with activity (2)'	System	20 Sep 2020 21:04:04

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-20T17:03:52', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'aa038c48-491c-409e-a7d7-3ddef7818b3c' User entered 'No (N)'	System	20 Sep 2020 21:04:04
	System	20 Sep 2020 21:04:04

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-20T17:03:54', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'aa038c48-491c-409e-a7d7-3ddef7818b3c' User entered 'No (N)'	System	20 Sep 2020 21:04:04
	System	20 Sep 2020 21:04:04

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-20T17:03:57', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'aa038c48-491c-409e-a7d7-3ddef7818b3c' User entered 'None (1)'	System	20 Sep 2020 21:04:04
	System	20 Sep 2020 21:04:04

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-20T17:03:59', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'aa038c48-491c-409e-a7d7-3ddef7818b3c' User entered '20 Sep 2020 17:03'	System	20 Sep 2020 21:04:04
	System	20 Sep 2020 21:04:04

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
Data entry locked.	System	18 Sep 2020 15:40:31
User entered 'Day 4'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-22T00:00:32', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bb456251-16f5-438f-9fdd-446811fd1ab1'	System	22 Sep 2020 04:00:47
User entered 'Does not interfere with activity (2)'	System	22 Sep 2020 04:00:47

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-22T00:00:34', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bb456251-16f5-438f-9fdd-446811fd1ab1' User entered 'No (N)'	System	22 Sep 2020 04:00:47
	System	22 Sep 2020 04:00:47

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-22T00:00:39', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bb456251-16f5-438f-9fdd-446811fd1ab1' User entered 'No (N)'	System	22 Sep 2020 04:00:47
	System	22 Sep 2020 04:00:47

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-22T00:00:42', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bb456251-16f5-438f-9fdd-446811fd1ab1'	System	22 Sep 2020 04:00:47
User entered 'None (1)'	System	22 Sep 2020 04:00:47

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-22T00:00:44', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bb456251-16f5-438f-9fdd-446811fd1ab1' User entered '22 Sep 2020 00:00'	System	22 Sep 2020 04:00:47
	System	22 Sep 2020 04:00:47

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
Data entry locked.	System	18 Sep 2020 15:40:31
User entered 'Day 5'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T02:55:30', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'cde116d1-6dbd-4104-9d73-41ef8c3a5f6d' User entered 'Does not interfere with activity (2)'	System	23 Sep 2020 06:55:39
	System	23 Sep 2020 06:55:39

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T02:55:31', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'cde116d1-6dbd-4104-9d73-41ef8c3a5f6d' User entered 'No (N)'	System	23 Sep 2020 06:55:39
	System	23 Sep 2020 06:55:39

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T02:55:33', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'cde116d1-6dbd-4104-9d73-41ef8c3a5f6d' User entered 'No (N)'	System	23 Sep 2020 06:55:39
	System	23 Sep 2020 06:55:39

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T02:55:35', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'cde116d1-6dbd-4104-9d73-41ef8c3a5f6d' User entered 'None (1)'	System	23 Sep 2020 06:55:39
	System	23 Sep 2020 06:55:39

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T02:55:37', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'cde116d1-6dbd-4104-9d73-41ef8c3a5f6d' User entered '23 Sep 2020 02:55'	System	23 Sep 2020 06:55:39
	System	23 Sep 2020 06:55:39

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
Data entry locked.	System	18 Sep 2020 15:40:31
User entered 'Day 6'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T21:41:37', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'b043ef12-915c-46ed-a9f5-2f3d50a0b4f6'	System	24 Sep 2020 01:41:48
User entered 'Does not interfere with activity (2)'	System	24 Sep 2020 01:41:48

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T21:41:39', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'b043ef12-915c-46ed-a9f5-2f3d50a0b4f6'	System	24 Sep 2020 01:41:48
User entered 'No (N)'	System	24 Sep 2020 01:41:48

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T21:41:41', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'b043ef12-915c-46ed-a9f5-2f3d50a0b4f6'	System	24 Sep 2020 01:41:48
User entered 'No (N)'	System	24 Sep 2020 01:41:48

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T21:41:43', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'b043ef12-915c-46ed-a9f5-2f3d50a0b4f6'	System	24 Sep 2020 01:41:48
User entered 'None (1)'	System	24 Sep 2020 01:41:48

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T21:41:45', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'b043ef12-915c-46ed-a9f5-2f3d50a0b4f6' User entered '23 Sep 2020 21:41'	System	24 Sep 2020 01:41:48
	System	24 Sep 2020 01:41:48

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
Data entry locked.	System	18 Sep 2020 15:40:31
User entered 'Day 7'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-24T23:59:30', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ba2b63c5-568b-40d7-b8b7-2d24ba112f0c'	System	25 Sep 2020 03:59:45
User entered 'Does not interfere with activity (2)'	System	25 Sep 2020 03:59:45

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:54

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-24T23:59:31', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ba2b63c5-568b-40d7-b8b7-2d24ba112f0c' User entered 'No (N)'	System	25 Sep 2020 03:59:45
	System	25 Sep 2020 03:59:45

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-24T23:59:33', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ba2b63c5-568b-40d7-b8b7-2d24ba112f0c' User entered 'No (N)'	System	25 Sep 2020 03:59:45
	System	25 Sep 2020 03:59:45

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-24T23:59:34', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ba2b63c5-568b-40d7-b8b7-2d24ba112f0c'	System	25 Sep 2020 03:59:45
User entered 'None (1)'	System	25 Sep 2020 03:59:45

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-24T23:59:36', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ba2b63c5-568b-40d7-b8b7-2d24ba112f0c' User entered '24 Sep 2020 23:59'	System	25 Sep 2020 03:59:45
	System	25 Sep 2020 03:59:45

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
Data entry locked.	System	18 Sep 2020 15:40:31
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T11:46:22', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '2764e089-6451-44c8-a885-977adb697620' User entered 'None (0)'	System	18 Sep 2020 15:46:53
	System	18 Sep 2020 15:46:53

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T11:46:24', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '2764e089-6451-44c8-a885-977adb697620' User entered 'None (0)'	System	18 Sep 2020 15:46:53
	System	18 Sep 2020 15:46:53

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T11:46:26', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '2764e089-6451-44c8-a885-977adb697620' User entered 'None (0)'	System	18 Sep 2020 15:46:53
	System	18 Sep 2020 15:46:53

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T11:46:29', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '2764e089-6451-44c8-a885-977adb697620' User entered 'None (0)'	System	18 Sep 2020 15:46:53
	System	18 Sep 2020 15:46:53

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T11:46:36', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '2764e089-6451-44c8-a885-977adb697620' User entered 'None (0)'	System	18 Sep 2020 15:46:53
	System	18 Sep 2020 15:46:53

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T11:46:40', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '2764e089-6451-44c8-a885-977adb697620' User entered 'None (0)'	System	18 Sep 2020 15:46:53
	System	18 Sep 2020 15:46:53

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

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)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T11:46:45', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '2764e089-6451-44c8-a885-977adb697620' User entered 'No (N)'	System	18 Sep 2020 15:46:53
	System	18 Sep 2020 15:46:53

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T11:46:49', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '2764e089-6451-44c8-a885-977adb697620' User entered '18 Sep 2020 11:46'	System	18 Sep 2020 15:46:53
	System	18 Sep 2020 15:46:53

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '18 Sep 2020 11:34'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '18 Sep 2020 14:04'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
Data entry locked.	System	18 Sep 2020 15:40:31
User entered 'Day 1, after vaccination (at home)'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T20:50:58', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6658dfb8-b095-4b8d-9112-c0e729495f7e'	System	19 Sep 2020 00:51:20
User entered 'No interference with activity (1)'	System	19 Sep 2020 00:51:20

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T20:51:01', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6658dfb8-b095-4b8d-9112-c0e729495f7e' User entered 'None (0)'	System	19 Sep 2020 00:51:20
	System	19 Sep 2020 00:51:20

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T20:51:05', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6658dfb8-b095-4b8d-9112-c0e729495f7e' User entered 'None (0)'	System	19 Sep 2020 00:51:20
	System	19 Sep 2020 00:51:20

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T20:51:07', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6658dfb8-b095-4b8d-9112-c0e729495f7e' User entered 'None (0)'	System	19 Sep 2020 00:51:20
	System	19 Sep 2020 00:51:20

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T20:51:09', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6658dfb8-b095-4b8d-9112-c0e729495f7e' User entered 'None (0)'	System	19 Sep 2020 00:51:20
	System	19 Sep 2020 00:51:20

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T20:51:11', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6658dfb8-b095-4b8d-9112-c0e729495f7e' User entered 'None (0)'	System	19 Sep 2020 00:51:20
	System	19 Sep 2020 00:51:20

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

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)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T20:51:14', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6658dfb8-b095-4b8d-9112-c0e729495f7e' User entered 'No (N)'	System	19 Sep 2020 00:51:20
	System	19 Sep 2020 00:51:20

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-18T20:51:15', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6658dfb8-b095-4b8d-9112-c0e729495f7e' User entered '18 Sep 2020 20:51'	System	19 Sep 2020 00:51:20
	System	19 Sep 2020 00:51:20

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '18 Sep 2020 14:59'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '19 Sep 2020 11:59'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
Data entry locked.	System	18 Sep 2020 15:40:31
User entered 'Day 2'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-19T12:54:50', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'c8cd217d-e6f1-4268-a65b-272dcaed2cf2'	System	19 Sep 2020 16:55:24
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	19 Sep 2020 16:55:24

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-19T12:54:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'c8cd217d-e6f1-4268-a65b-272dcaed2cf2'	System	19 Sep 2020 16:55:24
User entered 'Some interference with activity (2)'	System	19 Sep 2020 16:55:24

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-19T12:54:58', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'c8cd217d-e6f1-4268-a65b-272dcaed2cf2'	System	19 Sep 2020 16:55:24
User entered 'Significant; prevents daily activity (3)'	System	19 Sep 2020 16:55:24

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-19T12:55:00', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'c8cd217d-e6f1-4268-a65b-272dcaed2cf2'	System	19 Sep 2020 16:55:24
User entered 'Significant; prevents daily activity (3)'	System	19 Sep 2020 16:55:24

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-19T12:55:05', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'c8cd217d-e6f1-4268-a65b-272dcaed2cf2'	System	19 Sep 2020 16:55:24
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	19 Sep 2020 16:55:24

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-19T12:55:11', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'c8cd217d-e6f1-4268-a65b-272dcaed2cf2'	System	19 Sep 2020 16:55:24
User entered 'Some interference with activity not requiring medical attention (2)'	System	19 Sep 2020 16:55:24

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:54

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)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-19T12:55:15', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'c8cd217d-e6f1-4268-a65b-272dcaed2cf2'	System	19 Sep 2020 16:55:24
User entered 'Yes (Y)'	System	19 Sep 2020 16:55:24

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-19T12:55:20', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'c8cd217d-e6f1-4268-a65b-272dcaed2cf2'	System	19 Sep 2020 16:55:24
User entered '19 Sep 2020 12:55'	System	19 Sep 2020 16:55:24

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
Data entry locked.	System	18 Sep 2020 15:40:31
User entered 'Day 3'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-20T17:03:05', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ecec401d-b023-4c29-9af5-16ea0b8634e1' User entered 'None (0)'	System	20 Sep 2020 21:03:50
	System	20 Sep 2020 21:03:50

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-20T17:03:08', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ecec401d-b023-4c29-9af5-16ea0b8634e1' User entered 'Some interference with activity (2)'	System	20 Sep 2020 21:03:50
	System	20 Sep 2020 21:03:50

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-20T17:03:40', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ecec401d-b023-4c29-9af5-16ea0b8634e1' User entered 'Some interference with activity (2)'	System	20 Sep 2020 21:03:50
	System	20 Sep 2020 21:03:50

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-20T17:03:37', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ecec401d-b023-4c29-9af5-16ea0b8634e1' User entered 'Some interference with activity (2)'	System	20 Sep 2020 21:03:50
	System	20 Sep 2020 21:03:50

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-20T17:03:18', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ecec401d-b023-4c29-9af5-16ea0b8634e1' User entered 'None (0)'	System	20 Sep 2020 21:03:50
	System	20 Sep 2020 21:03:50

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-20T17:03:22', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ecec401d-b023-4c29-9af5-16ea0b8634e1'	System	20 Sep 2020 21:03:50
User entered 'No interference with activity (1)'	System	20 Sep 2020 21:03:50

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:54

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)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-20T17:03:25', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ecec401d-b023-4c29-9af5-16ea0b8634e1' User entered 'No (N)'	System	20 Sep 2020 21:03:50
	System	20 Sep 2020 21:03:50

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-20T17:03:45', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ecec401d-b023-4c29-9af5-16ea0b8634e1' User entered '20 Sep 2020 17:03'	System	20 Sep 2020 21:03:50
	System	20 Sep 2020 21:03:50

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '20 Sep 2020 12:00'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '21 Sep 2020 11:59'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
Data entry locked.	System	18 Sep 2020 15:40:31
User entered 'Day 4'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-22T00:00:48', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a6175b2f-319e-4401-bb67-ff662e39c838'	System	22 Sep 2020 04:01:14
User entered 'No interference with activity (1)'	System	22 Sep 2020 04:01:14

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-22T00:00:50', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a6175b2f-319e-4401-bb67-ff662e39c838'	System	22 Sep 2020 04:01:14
User entered 'No interference with activity (1)'	System	22 Sep 2020 04:01:14

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-22T00:00:53', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a6175b2f-319e-4401-bb67-ff662e39c838' User entered 'None (0)'	System	22 Sep 2020 04:01:14
	System	22 Sep 2020 04:01:14

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-22T00:00:54', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a6175b2f-319e-4401-bb67-ff662e39c838' User entered 'None (0)'	System	22 Sep 2020 04:01:14
	System	22 Sep 2020 04:01:14

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-22T00:01:00', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a6175b2f-319e-4401-bb67-ff662e39c838'	System	22 Sep 2020 04:01:14
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	22 Sep 2020 04:01:14

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-22T00:01:05', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a6175b2f-319e-4401-bb67-ff662e39c838' User entered 'None (0)'	System	22 Sep 2020 04:01:14
	System	22 Sep 2020 04:01:14

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:54

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)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-22T00:01:07', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a6175b2f-319e-4401-bb67-ff662e39c838'	System	22 Sep 2020 04:01:14
User entered 'Yes (Y)'	System	22 Sep 2020 04:01:14

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-22T00:01:10', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a6175b2f-319e-4401-bb67-ff662e39c838' User entered '22 Sep 2020 00:01'	System	22 Sep 2020 04:01:14
	System	22 Sep 2020 04:01:14

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '21 Sep 2020 12:00'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '22 Sep 2020 11:59'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
Data entry locked.	System	18 Sep 2020 15:40:31
User entered 'Day 5'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T02:55:41', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'fea74e08-fdd4-481d-b726-2d9a489b85a2' User entered 'None (0)'	System	23 Sep 2020 06:56:05
	System	23 Sep 2020 06:56:05

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T02:55:44', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'fea74e08-fdd4-481d-b726-2d9a489b85a2'	System	23 Sep 2020 06:56:05
User entered 'Some interference with activity (2)'	System	23 Sep 2020 06:56:05

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T02:55:51', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'fea74e08-fdd4-481d-b726-2d9a489b85a2' User entered 'None (0)'	System	23 Sep 2020 06:56:05
	System	23 Sep 2020 06:56:05

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T02:55:53', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'fea74e08-fdd4-481d-b726-2d9a489b85a2' User entered 'None (0)'	System	23 Sep 2020 06:56:05
	System	23 Sep 2020 06:56:05

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T02:55:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'fea74e08-fdd4-481d-b726-2d9a489b85a2'	System	23 Sep 2020 06:56:05
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	23 Sep 2020 06:56:05

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T02:55:57', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'fea74e08-fdd4-481d-b726-2d9a489b85a2' User entered 'None (0)'	System	23 Sep 2020 06:56:05
	System	23 Sep 2020 06:56:05

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:54

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)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T02:56:00', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'fea74e08-fdd4-481d-b726-2d9a489b85a2' User entered 'No (N)'	System	23 Sep 2020 06:56:05
	System	23 Sep 2020 06:56:05

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T02:56:02', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'fea74e08-fdd4-481d-b726-2d9a489b85a2' User entered '23 Sep 2020 02:56'	System	23 Sep 2020 06:56:05
	System	23 Sep 2020 06:56:05

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '22 Sep 2020 12:00'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '23 Sep 2020 11:59'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
Data entry locked.	System	18 Sep 2020 15:40:31
User entered 'Day 6'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T21:41:51', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '3ac4d297-2993-448a-a72b-0002f2aa7daa'	System	24 Sep 2020 01:42:17
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	24 Sep 2020 01:42:17

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T21:41:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '3ac4d297-2993-448a-a72b-0002f2aa7daa'	System	24 Sep 2020 01:42:17
User entered 'Some interference with activity (2)'	System	24 Sep 2020 01:42:17

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T21:41:57', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '3ac4d297-2993-448a-a72b-0002f2aa7daa' User entered 'None (0)'	System	24 Sep 2020 01:42:17
	System	24 Sep 2020 01:42:17

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T21:41:59', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '3ac4d297-2993-448a-a72b-0002f2aa7daa' User entered 'None (0)'	System	24 Sep 2020 01:42:17
	System	24 Sep 2020 01:42:17

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T21:42:06', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '3ac4d297-2993-448a-a72b-0002f2aa7daa'	System	24 Sep 2020 01:42:17
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	24 Sep 2020 01:42:17

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T21:42:08', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '3ac4d297-2993-448a-a72b-0002f2aa7daa' User entered 'None (0)'	System	24 Sep 2020 01:42:17
	System	24 Sep 2020 01:42:17

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:54

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)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T21:42:11', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '3ac4d297-2993-448a-a72b-0002f2aa7daa'	System	24 Sep 2020 01:42:17
User entered 'Yes (Y)'	System	24 Sep 2020 01:42:17

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-23T21:42:13', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '3ac4d297-2993-448a-a72b-0002f2aa7daa' User entered '23 Sep 2020 21:42'	System	24 Sep 2020 01:42:17
	System	24 Sep 2020 01:42:17

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '23 Sep 2020 12:00'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '24 Sep 2020 11:59'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
Data entry locked.	System	18 Sep 2020 15:40:31
User entered 'Day 7'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:54

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-24T23:59:40', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '831efed2-845a-4f68-bf31-558134f28e6b' User entered 'None (0)'	System	25 Sep 2020 04:00:14
	System	25 Sep 2020 04:00:14

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:54

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-24T23:59:42', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '831efed2-845a-4f68-bf31-558134f28e6b' User entered 'None (0)'	System	25 Sep 2020 04:00:14
	System	25 Sep 2020 04:00:14

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:54

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-24T23:59:44', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '831efed2-845a-4f68-bf31-558134f28e6b' User entered 'None (0)'	System	25 Sep 2020 04:00:14
	System	25 Sep 2020 04:00:14

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:54

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-24T23:59:45', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '831efed2-845a-4f68-bf31-558134f28e6b' User entered 'None (0)'	System	25 Sep 2020 04:00:14
	System	25 Sep 2020 04:00:14

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:54

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-24T23:59:47', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '831efed2-845a-4f68-bf31-558134f28e6b' User entered 'None (0)'	System	25 Sep 2020 04:00:14
	System	25 Sep 2020 04:00:14

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:54

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-24T23:59:48', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '831efed2-845a-4f68-bf31-558134f28e6b' User entered 'None (0)'	System	25 Sep 2020 04:00:14
	System	25 Sep 2020 04:00:14

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:54

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)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-24T23:59:53', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '831efed2-845a-4f68-bf31-558134f28e6b' User entered 'No (N)'	System	25 Sep 2020 04:00:14
	System	25 Sep 2020 04:00:14

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-24T23:59:56', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '831efed2-845a-4f68-bf31-558134f28e6b' User entered '24 Sep 2020 23:59'	System	25 Sep 2020 04:00:14
	System	25 Sep 2020 04:00:14

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '24 Sep 2020 12:00'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '25 Sep 2020 11:59'	System	18 Sep 2020 15:40:31

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
Data entry locked.	System	24 Sep 2020 01:41:48
User entered 'Day 8'	System	24 Sep 2020 01:41:48

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 17:35:54

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-26T00:00:07', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '83c14aa5-3644-4104-ae30-07d536c4a23d' User entered 'None (1)'	System	26 Sep 2020 04:00:16
	System	26 Sep 2020 04:00:16

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 17:35:54

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-26T00:00:11', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '83c14aa5-3644-4104-ae30-07d536c4a23d' User entered '26 Sep 2020 00:00'	System	26 Sep 2020 04:00:16
	System	26 Sep 2020 04:00:16

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 01:41:48

US3432229

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 01:41:48

US3432229

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
Data entry locked.	System	24 Sep 2020 01:41:37
User entered 'Day 8'	System	24 Sep 2020 01:41:37

US3432229

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:35:54

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)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-26T00:00:16', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '97340cda-ab22-4ee8-8bc3-eb9e48dd8063' User entered 'Yes (Y)'	System	26 Sep 2020 04:00:26
	System	26 Sep 2020 04:00:26

US3432229

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:35:54

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-09-26T00:00:19', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '97340cda-ab22-4ee8-8bc3-eb9e48dd8063' User entered '26 Sep 2020 00:00'	System	26 Sep 2020 04:00:26
	System	26 Sep 2020 04:00:26

US3432229

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:35:54

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 01:41:37

US3432229

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:35:54

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:00:46
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 01:41:37

US3432229

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 20:14:12

US3432229

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '25 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 20:14:12

US3432229

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	25 Sep 2020 20:14:12

US3432229

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 20:14:12

US3432229

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 20:14:24

US3432229

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'I'	System	25 Sep 2020 20:14:24

US3432229

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 19:09:22

US3432229

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '2 Oct 2020'	(b) (4), (b) (6)	02 Oct 2020 19:09:22

US3432229

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Oct 2020 19:09:22

US3432229

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	(b) (4), (b) (6)	02 Oct 2020 19:09:22

US3432229

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Oct 2020 19:09:27

US3432229

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'I'	System	02 Oct 2020 19:09:27

US3432229

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 23:20:14

US3432229

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '9 Oct 2020'	(b) (4), (b) (6)	09 Oct 2020 23:20:14

US3432229

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Oct 2020 23:20:14

US3432229

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 23:20:14

US3432229

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 23:20:49

US3432229

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'I'	System	09 Oct 2020 23:20:49

US3432229

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 16OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 11:40:37
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 16OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'collected' (Site from DM).	Monica Feeley (b) (4)	10 Nov 2020 21:54:19
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 16OCT2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 06:14:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 15:51:38

US3432229

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 15:51:38

US3432229

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Home (Home)'	(b) (4), (b) (6)	16 Oct 2020 15:51:38

US3432229

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'VISIT3'	System	16 Oct 2020 15:51:38

US3432229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 15:53:18

US3432229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '16 Oct 2020'	(b) (4), (b) (6)	16 Oct 2020 15:53:18

US3432229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '11:24'	(b) (4), (b) (6)	16 Oct 2020 15:53:18

US3432229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered '16 Oct 2020 11:24'	System	16 Oct 2020 15:53:18

US3432229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '98.7' F	(b) (4), (b) (6)	16 Oct 2020 15:53:18

US3432229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Oral (Oral)'	(b) (4), (b) (6)	16 Oct 2020 15:53:18

US3432229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 15:53:18

US3432229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '86'	(b) (4), (b) (6)	16 Oct 2020 15:53:18

US3432229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'bpm'	System	16 Oct 2020 15:53:18

US3432229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '16'	(b) (4), (b) (6)	16 Oct 2020 15:53:18

US3432229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'breaths/min'	System	16 Oct 2020 15:53:18

US3432229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '104' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Oct 2020 15:54:20
User entered '105'	(b) (4), (b) (6)	16 Oct 2020 15:53:18

US3432229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'mmHg'	System	16 Oct 2020 15:53:18

US3432229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	16 Nov 2020 13:50:05
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System).	Monica Feeley (b) (4)	10 Nov 2020 21:55:13
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		16 Oct 2020 15:53:18
User entered '58'	(b) (4), (b) (6)	16 Oct 2020 15:53:18

US3432229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'mmHg'	System	16 Oct 2020 15:53:18

US3432229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37

US3432229

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37

US3432229

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:35:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'No (N)'	(b) (4), (b) (6)	16 Oct 2020 15:54:46

US3432229

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:35:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 15:54:46

US3432229

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Yes (Y)'	Monica Feeley (b) (4)	10 Nov 2020 21:54:51

US3432229

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:54

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '16 Oct 2020'	Monica Feeley (b) (4)	10 Nov 2020 21:54:51

US3432229

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:54

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '11:39'	Monica Feeley (b) (4)	10 Nov 2020 21:54:51

US3432229

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered '16 Oct 2020 11:39'	System	10 Nov 2020 21:54:51

US3432229

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Oct 2020 15:54:53

US3432229

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'I'	System	16 Oct 2020 15:54:53

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
Data entry locked.	System	21 Aug 2020 17:08:42
User entered 'Day 64'	System	21 Aug 2020 17:08:42

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-23T12:00:19', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '08e519a4-6f70-4d8f-bf84-69cc2eb4aedef' User entered 'No (N)'	System	23 Oct 2020 16:00:42
	System	23 Oct 2020 16:00:42

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-23T12:00:23', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '08e519a4-6f70-4d8f-bf84-69cc2eb4aedd'	System	23 Oct 2020 16:00:42
User entered 'No (N)'	System	23 Oct 2020 16:00:42

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-23T12:00:26', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '08e519a4-6f70-4d8f-bf84-69cc2eb4aedd'	System	23 Oct 2020 16:00:42
User entered '23 Oct 2020 12:00:26'	System	23 Oct 2020 16:00:42

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
Data entry locked.	System	21 Aug 2020 17:08:42
User entered '21 Oct 2020 00:01'	System	21 Aug 2020 17:08:42

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
Data entry locked.	System	21 Aug 2020 17:08:42
User entered '25 Oct 2020 23:59'	System	21 Aug 2020 17:08:42

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
Data entry locked.	System	21 Aug 2020 17:08:42
User entered 'Day 71'	System	21 Aug 2020 17:08:42

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:15', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26'	System	31 Oct 2020 22:45:34
User entered 'Yes (Y)'	System	31 Oct 2020 22:45:34

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:17', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26'	System	31 Oct 2020 22:45:34
User entered 'No (N)'	System	31 Oct 2020 22:45:34

US3432229

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:48', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26'	System	31 Oct 2020 22:45:34
User entered 'Yes (Y)'	System	31 Oct 2020 22:45:34

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' User entered '0'	System	31 Oct 2020 22:45:34
	System	31 Oct 2020 22:45:34

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' User entered '0'	System	31 Oct 2020 22:45:34
	System	31 Oct 2020 22:45:34

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' User entered '0'	System	31 Oct 2020 22:45:34
	System	31 Oct 2020 22:45:34

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' User entered '0'	System	31 Oct 2020 22:45:34
	System	31 Oct 2020 22:45:34

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' User entered '0'	System	31 Oct 2020 22:45:34
	System	31 Oct 2020 22:45:34

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' User entered '0'	System	31 Oct 2020 22:45:34
	System	31 Oct 2020 22:45:34

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' User entered '0'	System	31 Oct 2020 22:45:34
	System	31 Oct 2020 22:45:34

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' User entered '0'	System	31 Oct 2020 22:45:34
	System	31 Oct 2020 22:45:34

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' User entered '0'	System	31 Oct 2020 22:45:34
	System	31 Oct 2020 22:45:34

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' User entered '0'	System	31 Oct 2020 22:45:34
	System	31 Oct 2020 22:45:34

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' User entered '0'	System	31 Oct 2020 22:45:34
	System	31 Oct 2020 22:45:34

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
User closed query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM). Query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'Did not meet AE reporting criteria' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 15:48:35
User opened query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 15:26:56
User opened query 'Per DM CLR: Experienced any new COVID-19 symptoms since last questionnaire or study contact?; and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 15:16:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26'	System	31 Oct 2020 22:45:34
User entered '1'	System	31 Oct 2020 22:45:34

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' User entered '0'	System	31 Oct 2020 22:45:34
	System	31 Oct 2020 22:45:34

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' User entered '0'	System	31 Oct 2020 22:45:34
	System	31 Oct 2020 22:45:34

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' User entered '0'	System	31 Oct 2020 22:45:34
	System	31 Oct 2020 22:45:34

US3432229

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:35:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' User entered '0'	System	31 Oct 2020 22:45:34
	System	31 Oct 2020 22:45:34

US3432229

Folder: Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:44:55', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' User entered '0'	System	31 Oct 2020 22:45:34
	System	31 Oct 2020 22:45:34

US3432229

Folder: Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:45:09', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26'	System	31 Oct 2020 22:45:34
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	31 Oct 2020 22:45:34

US3432229

Folder: Safety Follow Up Diary (1)

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Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:45:14', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26'	System	31 Oct 2020 22:45:34
User entered 'Yes (Y)'	System	31 Oct 2020 22:45:34

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:45:18', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26'	System	31 Oct 2020 22:45:34
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	31 Oct 2020 22:45:34

US3432229

Folder: Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-10-31T18:45:23', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '279e2bb4-392e-4a16-bf8c-b224da290c26' User entered '31 Oct 2020 18:45:23'	System	31 Oct 2020 22:45:34
	System	31 Oct 2020 22:45:34

US3432229

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
Data entry locked.	System	21 Aug 2020 17:08:42
User entered '28 Oct 2020 00:01'	System	21 Aug 2020 17:08:42

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
Data entry locked.	System	21 Aug 2020 17:08:42
User entered '01 Nov 2020 23:59'	System	21 Aug 2020 17:08:42

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
Data entry locked.	System	21 Aug 2020 17:08:42
User entered 'Day 78'	System	21 Aug 2020 17:08:42

US3432229

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Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-11-08T11:59:13', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6cc877f6-6ab3-4d12-a268-dabf7d64b86a' User entered 'No (N)'	System	08 Nov 2020 16:59:21
	System	08 Nov 2020 16:59:21

US3432229

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-11-08T11:59:15', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6cc877f6-6ab3-4d12-a268-dabf7d64b86a' User entered 'No (N)'	System	08 Nov 2020 16:59:21
	System	08 Nov 2020 16:59:21

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-11-08T11:59:17', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '6cc877f6-6ab3-4d12-a268-dabf7d64b86a' User entered '08 Nov 2020 11:59:17'	System	08 Nov 2020 16:59:21
	System	08 Nov 2020 16:59:21

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
Data entry locked.	System	21 Aug 2020 17:08:42
User entered '04 Nov 2020 00:01'	System	21 Aug 2020 17:08:42

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
Data entry locked.	System	21 Aug 2020 17:08:42
User entered '08 Nov 2020 23:59'	System	21 Aug 2020 17:08:42

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:32:22
Data entry locked.	System	21 Aug 2020 17:08:42
User entered 'Day 92'	System	21 Aug 2020 17:08:42

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:32:22

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:32:22

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:32:22

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:32:22

US3432229

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:35:54

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:32:22

US3432229

Folder: Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:32:22

US3432229

Folder: Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:32:22

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:32:22

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:32:22

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:32:22

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:32:22

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:32:22

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:32:22

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:32:22

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:32:22

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:32:22

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:32:22

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:32:22

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:32:22

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:32:22

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:32:22

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:32:22

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:32:22

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:32:22

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:32:22

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:32:22
Data entry locked.	System	21 Aug 2020 17:08:42
User entered '18 Nov 2020 00:01'	System	21 Aug 2020 17:08:42

US3432229

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:32:22
Data entry locked.	System	21 Aug 2020 17:08:42
User entered '22 Nov 2020 23:59'	System	21 Aug 2020 17:08:42

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 00:32:22

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-12-06T11:59:29', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ba3435f8-abaf-4bea-99b2-6c24af5ec6d4' User entered 'No (N)'	System	06 Dec 2020 16:59:38
	System	06 Dec 2020 16:59:38

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

Have you been exposed to someone with 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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-12-06T11:59:31', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ba3435f8-abaf-4bea-99b2-6c24af5ec6d4' User entered 'No (N)'	System	06 Dec 2020 16:59:38
	System	06 Dec 2020 16:59:38

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-12-06T11:59:34', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ba3435f8-abaf-4bea-99b2-6c24af5ec6d4' User entered '06 Dec 2020 11:59:34'	System	06 Dec 2020 16:59:38
	System	06 Dec 2020 16:59:38

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-12-15T18:45:39', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'adb266f4-3095-4372-86f6-ca4bb63f7371' User entered 'No (N)'	System	15 Dec 2020 23:45:54
	System	15 Dec 2020 23:45:54

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

Have you been exposed to someone with 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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-12-15T18:45:45', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'adb266f4-3095-4372-86f6-ca4bb63f7371' User entered 'No (N)'	System	15 Dec 2020 23:45:54

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-12-15T18:45:48', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'adb266f4-3095-4372-86f6-ca4bb63f7371' User entered '15 Dec 2020 18:45:48'	System	15 Dec 2020 23:45:54
	System	15 Dec 2020 23:45:54

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-12-22T12:00:29', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'd880c75b-6a7a-4526-bf55-b3da6d484c73'	System	22 Dec 2020 17:00:55
User entered 'Yes (Y)'	System	22 Dec 2020 17:00:55

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

Have you been exposed to someone with 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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-12-22T12:00:32', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'd880c75b-6a7a-4526-bf55-b3da6d484c73'	System	22 Dec 2020 17:00:55
User entered 'No (N)'	System	22 Dec 2020 17:00:55

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-12-22T12:00:34', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'd880c75b-6a7a-4526-bf55-b3da6d484c73'	System	22 Dec 2020 17:00:55
User entered 'No (N)'	System	22 Dec 2020 17:00:55

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-12-22T12:00:37', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'd880c75b-6a7a-4526-bf55-b3da6d484c73'	System	22 Dec 2020 17:00:55
User entered 'No (N)'	System	22 Dec 2020 17:00:55

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-12-22T12:00:39', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'd880c75b-6a7a-4526-bf55-b3da6d484c73' User entered '22 Dec 2020 12:00:39'	System	22 Dec 2020 17:00:55
	System	22 Dec 2020 17:00:55

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-12-27T10:54:23', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'f78d54e8-19c3-4093-8929-7d66947f3464' User entered 'No (N)'	System	27 Dec 2020 15:54:47
	System	27 Dec 2020 15:54:47

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

Have you been exposed to someone with 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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-12-27T10:54:28', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'f78d54e8-19c3-4093-8929-7d66947f3464' User entered 'Yes (Y)'	System	27 Dec 2020 15:54:47
	System	27 Dec 2020 15:54:47

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-12-27T10:54:35', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'f78d54e8-19c3-4093-8929-7d66947f3464'	System	27 Dec 2020 15:54:47
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Dec 2020 15:54:47

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2020-12-27T10:54:37', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'f78d54e8-19c3-4093-8929-7d66947f3464' User entered '27 Dec 2020 10:54:37'	System	27 Dec 2020 15:54:47
	System	27 Dec 2020 15:54:47

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-01-06T17:59:26', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ec46e01d-f794-4932-bd28-539d3d302fde' User entered 'Yes (Y)'	System	06 Jan 2021 23:00:04
	System	06 Jan 2021 23:00:04

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

Have you been exposed to someone with 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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-01-06T17:59:22', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ec46e01d-f794-4932-bd28-539d3d302fde' User entered 'No (N)'	System	06 Jan 2021 23:00:04

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-01-06T17:59:35', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ec46e01d-f794-4932-bd28-539d3d302fde' User entered 'Yes (Y)'	System	06 Jan 2021 23:00:04
	System	06 Jan 2021 23:00:04

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-01-06T17:59:41', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ec46e01d-f794-4932-bd28-539d3d302fde' User entered '0'	System	06 Jan 2021 23:00:04

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-01-06T17:59:41', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ec46e01d-f794-4932-bd28-539d3d302fde' User entered '0'	System	06 Jan 2021 23:00:04

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-01-06T17:59:41', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ec46e01d-f794-4932-bd28-539d3d302fde' User entered '0'	System	06 Jan 2021 23:00:04

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-01-06T17:59:41', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ec46e01d-f794-4932-bd28-539d3d302fde' User entered '0'	System	06 Jan 2021 23:00:04

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-01-06T17:59:41', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ec46e01d-f794-4932-bd28-539d3d302fde' User entered '0'	System	06 Jan 2021 23:00:04

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-01-06T17:59:41', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ec46e01d-f794-4932-bd28-539d3d302fde' User entered '0'	System	06 Jan 2021 23:00:04

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-01-06T17:59:41', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ec46e01d-f794-4932-bd28-539d3d302fde' User entered '0'	System	06 Jan 2021 23:00:04

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-01-06T17:59:41', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ec46e01d-f794-4932-bd28-539d3d302fde' User entered '0'	System	06 Jan 2021 23:00:04

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-01-06T17:59:41', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ec46e01d-f794-4932-bd28-539d3d302fde' User entered '0'	System	06 Jan 2021 23:00:04

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-01-06T17:59:41', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ec46e01d-f794-4932-bd28-539d3d302fde' User entered '0'	System	06 Jan 2021 23:00:04

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-01-06T17:59:41', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ec46e01d-f794-4932-bd28-539d3d302fde' User entered '0'	System	06 Jan 2021 23:00:04

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-01-06T17:59:41', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ec46e01d-f794-4932-bd28-539d3d302fde' User entered '0'	System	06 Jan 2021 23:00:04

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-01-06T17:59:41', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ec46e01d-f794-4932-bd28-539d3d302fde' User entered '0'	System	06 Jan 2021 23:00:04

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-01-06T17:59:41', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ec46e01d-f794-4932-bd28-539d3d302fde' User entered '0'	System	06 Jan 2021 23:00:04
	System	06 Jan 2021 23:00:04

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-01-06T17:59:41', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ec46e01d-f794-4932-bd28-539d3d302fde' User entered '1'	System	06 Jan 2021 23:00:04

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-01-06T17:59:41', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ec46e01d-f794-4932-bd28-539d3d302fde' User entered '0'	System	06 Jan 2021 23:00:04

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-01-06T17:59:41', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ec46e01d-f794-4932-bd28-539d3d302fde' User entered '1'	System	06 Jan 2021 23:00:04

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-01-06T17:59:44', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ec46e01d-f794-4932-bd28-539d3d302fde'	System	06 Jan 2021 23:00:04
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	06 Jan 2021 23:00:04

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-01-06T17:59:48', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ec46e01d-f794-4932-bd28-539d3d302fde'	System	06 Jan 2021 23:00:04
User entered 'No (N)'	System	06 Jan 2021 23:00:04

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-01-06T17:59:51', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'ec46e01d-f794-4932-bd28-539d3d302fde' User entered '06 Jan 2021 17:59:51'	System	06 Jan 2021 23:00:04
	System	06 Jan 2021 23:00:04

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-01-13T16:47:48', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'de765a85-0a0e-44b0-a93d-399e8f12766f' User entered 'No (N)'	System	13 Jan 2021 21:47:55
	System	13 Jan 2021 21:47:55

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

Have you been exposed to someone with 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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-01-13T16:47:51', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'de765a85-0a0e-44b0-a93d-399e8f12766f' User entered 'No (N)'	System	13 Jan 2021 21:47:55

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-01-13T16:47:53', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'de765a85-0a0e-44b0-a93d-399e8f12766f' User entered '13 Jan 2021 16:47:53'	System	13 Jan 2021 21:47:55
	System	13 Jan 2021 21:47:55

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-01-20T18:05:05', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '415d090d-7d0f-4b0f-a993-9ea0601ec79d' User entered 'No (N)'	System	20 Jan 2021 23:05:16
	System	20 Jan 2021 23:05:16

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

Have you been exposed to someone with 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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-01-20T18:05:09', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '415d090d-7d0f-4b0f-a993-9ea0601ec79d' User entered 'No (N)'	System	20 Jan 2021 23:05:16
	System	20 Jan 2021 23:05:16

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-01-20T18:05:11', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '415d090d-7d0f-4b0f-a993-9ea0601ec79d' User entered '20 Jan 2021 18:05:11'	System	20 Jan 2021 23:05:16
	System	20 Jan 2021 23:05:16

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-01-27T18:35:13', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '56f3f014-3d92-47d2-9760-efbdc3c3fb3e' User entered 'No (N)'	System	27 Jan 2021 23:35:24
	System	27 Jan 2021 23:35:24

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

Have you been exposed to someone with 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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-01-27T18:35:15', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '56f3f014-3d92-47d2-9760-efbdc3c3fb3e' User entered 'No (N)'	System	27 Jan 2021 23:35:24
	System	27 Jan 2021 23:35:24

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-01-27T18:35:18', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '56f3f014-3d92-47d2-9760-efbdc3c3fb3e' User entered '27 Jan 2021 18:35:18'	System	27 Jan 2021 23:35:24
	System	27 Jan 2021 23:35:24

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-02-04T12:18:04', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '343df24a-69ca-44d0-8164-bd48701cb503'	System	04 Feb 2021 17:18:12
User entered 'No (N)'	System	04 Feb 2021 17:18:12

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

Have you been exposed to someone with 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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-02-04T12:18:07', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '343df24a-69ca-44d0-8164-bd48701cb503'	System	04 Feb 2021 17:18:12
User entered 'No (N)'	System	04 Feb 2021 17:18:12

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-02-04T12:18:09', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '343df24a-69ca-44d0-8164-bd48701cb503' User entered '04 Feb 2021 12:18:09'	System	04 Feb 2021 17:18:12
	System	04 Feb 2021 17:18:12

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-02-09T12:26:59', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a232325d-32ee-4e65-882d-ac4f149375ae' User entered 'Yes (Y)'	System	09 Feb 2021 17:27:13
	System	09 Feb 2021 17:27:13

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

Have you been exposed to someone with 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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-02-09T12:27:02', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a232325d-32ee-4e65-882d-ac4f149375ae' User entered 'No (N)'	System	09 Feb 2021 17:27:13
	System	09 Feb 2021 17:27:13

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-02-09T12:27:05', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a232325d-32ee-4e65-882d-ac4f149375ae' User entered 'No (N)'	System	09 Feb 2021 17:27:13
	System	09 Feb 2021 17:27:13

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-02-09T12:27:08', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a232325d-32ee-4e65-882d-ac4f149375ae' User entered 'No (N)'	System	09 Feb 2021 17:27:13
	System	09 Feb 2021 17:27:13

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-02-09T12:27:11', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'a232325d-32ee-4e65-882d-ac4f149375ae' User entered '09 Feb 2021 12:27:11'	System	09 Feb 2021 17:27:13
	System	09 Feb 2021 17:27:13

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-02-17T10:23:21', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '7d472c86-db4f-4ff2-9caf-e481236fcea0' User entered 'No (N)'	System	17 Feb 2021 15:23:27
	System	17 Feb 2021 15:23:27

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

Have you been exposed to someone with 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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-02-17T10:23:23', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '7d472c86-db4f-4ff2-9caf-e481236fcea0' User entered 'No (N)'	System	17 Feb 2021 15:23:27

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-02-17T10:23:25', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '7d472c86-db4f-4ff2-9caf-e481236fcea0' User entered '17 Feb 2021 10:23:25'	System	17 Feb 2021 15:23:27

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-02-25T19:17:01', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bc5ecf57-d77c-4375-a754-cb1212987180' User entered 'No (N)'	System	26 Feb 2021 00:22:07
	System	26 Feb 2021 00:22:07

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

Have you been exposed to someone with 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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-02-25T19:17:09', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bc5ecf57-d77c-4375-a754-cb1212987180' User entered 'No (N)'	System	26 Feb 2021 00:22:07
	System	26 Feb 2021 00:22:07

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-02-25T19:17:11', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'bc5ecf57-d77c-4375-a754-cb1212987180' User entered '25 Feb 2021 19:17:11'	System	26 Feb 2021 00:22:07
	System	26 Feb 2021 00:22:07

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-03-04T12:26:13-05:00', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '7b75584b-bf74-475b-a8e4-c854c102e632'	System	04 Mar 2021 17:26:49
User entered 'No (N)'	System	04 Mar 2021 17:26:49

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

Have you been exposed to someone with 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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-03-04T12:26:14-05:00', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '7b75584b-bf74-475b-a8e4-c854c102e632'	System	04 Mar 2021 17:26:49
User entered 'No (N)'	System	04 Mar 2021 17:26:49

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-03-04T12:26:16-05:00', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '7b75584b-bf74-475b-a8e4-c854c102e632'	System	04 Mar 2021 17:26:49
User entered '04 Mar 2021 12:26:16'	System	04 Mar 2021 17:26:49

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-03-10T14:43:00-05:00', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '5c064748-6325-453a-a917-d1c866e2cb4c'	System	10 Mar 2021 19:43:12
User entered 'No (N)'	System	10 Mar 2021 19:43:12

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

Have you been exposed to someone with 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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-03-10T14:43:02-05:00', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '5c064748-6325-453a-a917-d1c866e2cb4c'	System	10 Mar 2021 19:43:12
User entered 'No (N)'	System	10 Mar 2021 19:43:12

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-03-10T14:43:04-05:00', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '5c064748-6325-453a-a917-d1c866e2cb4c' User entered '10 Mar 2021 14:43:04'	System	10 Mar 2021 19:43:12
	System	10 Mar 2021 19:43:12

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-03-24T20:01:42-04:00', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '335c4917-7c85-4c02-bbc7-2ff0cba899a3'	System	25 Mar 2021 00:03:18
User entered 'No (N)'	System	25 Mar 2021 00:03:18

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

Have you been exposed to someone with 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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-03-24T20:02:05-04:00', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '335c4917-7c85-4c02-bbc7-2ff0cba899a3'	System	25 Mar 2021 00:03:18
User entered 'No (N)'	System	25 Mar 2021 00:03:18

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-03-24T20:02:07-04:00', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '335c4917-7c85-4c02-bbc7-2ff0cba899a3'	System	25 Mar 2021 00:03:18
User entered '24 Mar 2021 20:02:07'	System	25 Mar 2021 00:03:18

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-03-31T17:59:17-04:00', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'fe4e0b6e-3917-4282-9f33-048d98a01c71'	System	31 Mar 2021 21:59:28
User entered 'No (N)'	System	31 Mar 2021 21:59:28

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

Have you been exposed to someone with 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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-03-31T17:59:19-04:00', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'fe4e0b6e-3917-4282-9f33-048d98a01c71'	System	31 Mar 2021 21:59:28
User entered 'No (N)'	System	31 Mar 2021 21:59:28

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-03-31T17:59:22-04:00', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: 'fe4e0b6e-3917-4282-9f33-048d98a01c71' User entered '31 Mar 2021 17:59:22'	System	31 Mar 2021 21:59:28
	System	31 Mar 2021 21:59:28

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-04-21T17:59:23-04:00', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '1431269d-44e7-4302-b842-3d17f5a10321'	System	21 Apr 2021 21:59:41
User entered 'No (N)'	System	21 Apr 2021 21:59:41

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

Have you been exposed to someone with 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 (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-04-21T17:59:26-04:00', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '1431269d-44e7-4302-b842-3d17f5a10321'	System	21 Apr 2021 21:59:41
User entered 'No (N)'	System	21 Apr 2021 21:59:41

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-04-21T17:59:30-04:00', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '1431269d-44e7-4302-b842-3d17f5a10321'	System	21 Apr 2021 21:59:41
User entered '21 Apr 2021 17:59:30'	System	21 Apr 2021 21:59:41

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 00:32:22

US3432229

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:35:54

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:32:22
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 00:32:22

US3432229

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:35:54

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 10:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-03-04T12:26:27-05:00', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '9bdb2794-a041-444a-9f4a-44c06e6b8c65'	System	04 Mar 2021 17:26:57
User entered 'No (N)'	System	04 Mar 2021 17:26:57

US3432229

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:35:54

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 10:30:31
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E1F7C6E4-7FFB-4617-8840-01541A6BD2F2)', Time: '2021-03-04T12:26:32-05:00', User OID: 'PatientReportedOutcome (US3432229)', ODM File OID: '9bdb2794-a041-444a-9f4a-44c06e6b8c65'	System	04 Mar 2021 17:26:57
User entered '04 Mar 2021 12:26:32'	System	04 Mar 2021 17:26:57

US3432229

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	19 Nov 2020 16:06:57

US3432229

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered '13 Nov 2020'	Phoebe Cunningham (b) (4)	19 Nov 2020 16:06:57

US3432229

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	19 Nov 2020 16:06:57

US3432229

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Called pt. 10NOV2020 a 10:08, 11NOV2020 at 10:00, 12NOV2020 at 10:17, amd 16NOV2020 at 13:52 and 18:34. Left vms at all calls but no contact made.'	Phoebe Cunningham (b) (4)	19 Nov 2020 16:06:57

US3432229

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Dec 2020 13:46:27

US3432229

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:12:37
User entered 'I'	System	14 Dec 2020 13:46:27

US3432229

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:28
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Dec 2020 20:12:33

US3432229

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:28
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '18 Dec 2020'	(b) (4), (b) (6)	21 Dec 2020 20:12:33

US3432229

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:28
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	21 Dec 2020 20:12:33

US3432229

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:28
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Called on 12/14 @ 8:47, 12/15 @ 11:35, 12/16 10:09, 12/18 @ 10:20'	(b) (4), (b) (6)	21 Dec 2020 20:12:33

US3432229

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:28
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Jan 2021 15:57:19

US3432229

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:28
User entered 'I'	System	13 Jan 2021 15:57:19

US3432229

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:28
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	19 Jan 2021 22:02:52

US3432229

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:28
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '19 Jan 2021'	Natalie Izaguirre (b) (4)	19 Jan 2021 22:02:52

US3432229

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:28
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Contact Made (CONTACT MADE)'	Natalie Izaguirre (b) (4)	19 Jan 2021 22:02:52

US3432229

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:28
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Natalie Izaguirre (b) (4)	19 Jan 2021 22:02:52

US3432229

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:28
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	19 Jan 2021 22:02:56

US3432229

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:28
User entered 'I'	System	19 Jan 2021 22:02:56

US3432229

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:32
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:42:10
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Feb 2021 17:53:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Feb 2021 17:53:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Bethany Evans (b) (4)	25 Feb 2021 17:53:58
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Feb 2021 15:34:29
User entered empty.	Tenaizus Woods (b) (4)	17 Feb 2021 15:34:29

US3432229

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:32
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:42:10
User entered '18 Feb 2021' reason for change: Data Entry Error	Bethany Evans (b) (4)	25 Feb 2021 17:53:58
User entered empty.	Tenaizus Woods (b) (4)	17 Feb 2021 15:34:29

US3432229

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:32
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:42:10
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	Bethany Evans (b) (4)	25 Feb 2021 17:53:58
User entered empty.	Tenaizus Woods (b) (4)	17 Feb 2021 15:34:29

US3432229

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:32
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:42:10
User entered 'PT not able to be reached for day 179 safety call. PT was called 17FEB21 at 10:34, 18FEB21 at 10:10 and 18FEB21 at 15:29.' reason for change: Data Entry Error	Bethany Evans (b) (4)	25 Feb 2021 17:53:58
User entered empty.	Tenaizus Woods (b) (4)	17 Feb 2021 15:34:29

US3432229

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:28
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:42:10
User entered 'Yes (Y)'	Bethany Evans (b) (4)	25 Feb 2021 17:54:05

US3432229

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:54

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:23:28
User entered 'I'	System	25 Feb 2021 17:54:05

US3432229

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered 'Yes (Y)'	(b) (4), (b) (6) [REDACTED]	22 Apr 2021 20:25:42

US3432229

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:54

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	26 Apr 2021 18:31:45
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'Participant is out of window due to delay in their schedule' (Site from System).	(b) (4), (b) (6)	22 Apr 2021 20:26:28
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	22 Apr 2021 20:25:42
User entered '22 Apr 2021'	(b) (4), (b) (6)	22 Apr 2021 20:25:42

US3432229

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:54

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	22 Apr 2021 20:25:42

US3432229

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:35:54

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	22 Apr 2021 20:25:42

US3432229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Apr 2021 20:28:29

US3432229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered '22 Apr 2021'	(b) (4), (b) (6) [REDACTED]	22 Apr 2021 20:28:29

US3432229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered '09:07'	(b) (4), (b) (6) [REDACTED]	22 Apr 2021 20:28:29

US3432229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
User entered '22 Apr 2021 09:07'	System	22 Apr 2021 20:28:29

US3432229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered '36.6' C	(b) (4), (b) (6) [REDACTED]	22 Apr 2021 20:28:29

US3432229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered 'Oral (Oral)'	(b) (4), (b) (6) [REDACTED]	22 Apr 2021 20:28:29

US3432229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered empty.	(b) (4), (b) (6) [REDACTED]	22 Apr 2021 20:28:29

US3432229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered '83'	(b) (4), (b) (6) [REDACTED]	22 Apr 2021 20:28:29

US3432229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	22 Apr 2021 20:28:29

US3432229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered '16'	(b) (4), (b) (6) [REDACTED]	22 Apr 2021 20:28:29

US3432229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	22 Apr 2021 20:28:29

US3432229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered '105'	(b) (4), (b) (6) [REDACTED]	22 Apr 2021 20:28:29

US3432229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Apr 2021 20:28:29

US3432229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered '71'	(b) (4), (b) (6) [REDACTED]	22 Apr 2021 20:28:29

US3432229

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:35:54

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	22 Apr 2021 20:28:29

US3432229

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:35:54

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered 'No (N)'	(b) (4), (b) (6) [REDACTED]	22 Apr 2021 20:28:41

US3432229

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:35:54

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered empty.	(b) (4), (b) (6) [REDACTED]	22 Apr 2021 20:28:41

US3432229

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Apr 2021 20:29:06

US3432229

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:54

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
User entered '22 Apr 2021'	(b) (4), (b) (6)	22 Apr 2021 20:29:06

US3432229

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:54

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
User entered '09:38'	(b) (4), (b) (6)	22 Apr 2021 20:29:06

US3432229

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
User entered '22 Apr 2021 09:38'	System	22 Apr 2021 20:29:06

US3432229

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered 'Yes (Y)'	Tenaizus Woods (b) (4) (b) (4)	16 Apr 2021 17:36:04

US3432229

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:54

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Apr 2021 17:36:04

US3432229

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered 'Yes (Y)'	Tenaizus Woods (b) (4) (b) (4)	16 Apr 2021 17:38:36

US3432229

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered '16 Apr 2021'	Tenaizus Woods (b) (4) (b) (4)	16 Apr 2021 17:38:36

US3432229

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered 'Contact Made (CONTACT MADE)'	Tenaizus Woods (b) (4) (b) (4)	16 Apr 2021 17:38:36

US3432229

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:35:54

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered empty.	Tenaizus Woods (b) (4) (b) (4)	16 Apr 2021 17:38:36

US3432229

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:54

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered 'Yes (Y)'	(b) (4), (b) (6) [REDACTED]	22 Apr 2021 16:21:49

US3432229

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:35:54

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Apr 2021 16:21:49

US3432229

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

Form: Visit Date

Generated On: 09 Jun 2021 17:35:54

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	19 Jan 2021 16:47:39

US3432229

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

Form: Visit Date

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '19 Jan 2021'	Natalie Izaguirre (b) (4)	19 Jan 2021 16:47:39

US3432229

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

Form: Visit Date

Generated On: 09 Jun 2021 17:35:54

[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 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Clinic (Clinic)'	Natalie Izaguirre (b) (4)	19 Jan 2021 16:47:39

US3432229

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

Form: Visit Date

Generated On: 09 Jun 2021 17:35:54

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User entered 'UNBLND_DECIDE'	System	19 Jan 2021 16:47:39

US3432229

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

Form: Unblinding

Generated On: 09 Jun 2021 17:35:54

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '19 Jan 2021'	Natalie Izaguirre (b) (4)	19 Jan 2021 16:51:19

US3432229

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

Form: Unblinding

Generated On: 09 Jun 2021 17:35:54

[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 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:42:10
User entered '0'	Bruce Bausk (b) (4)	31 Mar 2021 21:03:37
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 06:13:18

US3432229

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

Form: Unblinding

Generated On: 09 Jun 2021 17:35:54

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	19 Jan 2021 16:51:19

US3432229

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

Form: Unblinding

Generated On: 09 Jun 2021 17:35:54

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:42:10
User entered 'Amendment 6 or later (Amendment 6 or later)'	Bruce Bausk (b) (4)	31 Mar 2021 21:03:37
Amendment Manager inserted this DataPoint.	(b) (4)	
	System	06 Mar 2021 06:13:18

US3432229

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

Form: Unblinding

Generated On: 09 Jun 2021 17:35:54

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '19 Jan 2021'	Natalie Izaguirre (b) (4)	19 Jan 2021 16:51:19

US3432229

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

Form: Unblinding

Generated On: 09 Jun 2021 17:35:54

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'mRNA-1273 (mRNA-1273)'	Natalie Izaguirre (b) (4)	19 Jan 2021 16:51:19

US3432229

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

Form: Unblinding

Generated On: 09 Jun 2021 17:35:54

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 02:57:43
User entered 'mRNA-1273 (mRNA-1273)'	Natalie Izaguirre (b) (4)	19 Jan 2021 16:51:19

US3432229

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

Form: Unblinding

Generated On: 09 Jun 2021 17:35:54

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 02:57:43
User entered 'mRNA-1273 (mRNA-1273)'	Natalie Izaguirre (b) (4)	19 Jan 2021 16:51:19

US3432229

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

Form: Unblinding

Generated On: 09 Jun 2021 17:35:54

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	Natalie Izaguirre (b) (4)	19 Jan 2021 16:51:19

US3432229

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

Form: Unblinding

Generated On: 09 Jun 2021 17:35:54

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User entered empty.	System	19 Jan 2021 16:51:19

US3432229

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

Form: Unblinding

Generated On: 09 Jun 2021 17:35:54

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User entered empty.	System	19 Jan 2021 16:51:19

US3432229

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	19 Jan 2021 16:56:37

US3432229

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '19 Jan 2021'	Natalie Izaguirre (b) (4)	19 Jan 2021 16:56:37

US3432229

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:54

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '10:51'	Natalie Izaguirre (b) (4)	19 Jan 2021 16:56:37

US3432229

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User entered '19 Jan 2021 10:51'	System	19 Jan 2021 16:56:37

US3432229

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:35:54

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	19 Jan 2021 16:56:55

US3432229

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:35:54

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '19 Jan 2021'	Natalie Izaguirre (b) (4)	19 Jan 2021 16:56:55

US3432229

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:35:54

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '10:55'	Natalie Izaguirre (b) (4)	19 Jan 2021 16:56:55

US3432229

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:35:54

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:48:49
User entered '19 Jan 2021 10:55'	System	19 Jan 2021 16:56:55

US3432229

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:35:54

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:53:12
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:08
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	08 Sep 2020 13:43:55

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:54

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:24

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:54

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal conditions NEC, HLT: Gastrointestinal disorders NEC, PT: Gastrointestinal disorder, LLT: Gastrointestinal disorder - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 12:40:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 12:40:04
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal signs and symptoms NEC, PT: Abdominal discomfort, LLT: Gastrointestinal upset - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 15:34:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	08 Sep 2020 15:34:51
Data point term sent to Coder	System	08 Sep 2020 13:44:56
User entered 'transient gastrointestinal illness'	Xhoi Mitre (b) (4)	08 Sep 2020 13:44:55

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	Xhoi Mitre (b) (4)	08 Sep 2020 13:44:55

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:54

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	Xhoi Mitre (b) (4)	08 Sep 2020 13:44:55

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	Xhoi Mitre (b) (4)	08 Sep 2020 13:44:55

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '04 Sep 2020'	Xhoi Mitre (b) (4)	08 Sep 2020 13:44:55

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:54

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Xhoi Mitre (b) (4)	08 Sep 2020 13:44:55

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:54

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:24
User entered empty.	System	08 Sep 2020 13:44:55

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	Xhoi Mitre (b) (4)	08 Sep 2020 13:44:55

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:54

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '05 Sep 2020'	Xhoi Mitre (b) (4)	08 Sep 2020 13:44:55

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:54

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Xhoi Mitre (b) (4)	08 Sep 2020 13:44:55

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:54

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:24
User entered empty.	System	08 Sep 2020 13:44:55

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:54

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Grade 1/Mild (Grade 1/Mild)'	Xhoi Mitre (b) (4)	08 Sep 2020 13:44:55

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	Xhoi Mitre (b) (4)	08 Sep 2020 13:44:55

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:54

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	Xhoi Mitre (b) (4)	08 Sep 2020 13:44:55

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:54

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	Xhoi Mitre (b) (4)	08 Sep 2020 13:44:55

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	Xhoi Mitre (b) (4)	08 Sep 2020 13:44:55

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:54

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Xhoi Mitre (b) (4)	08 Sep 2020 13:44:55

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:54

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Xhoi Mitre (b) (4)	08 Sep 2020 13:44:55

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:54

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Xhoi Mitre (b) (4)	08 Sep 2020 13:44:55

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:54

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Xhoi Mitre (b) (4)	08 Sep 2020 13:44:55

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	Xhoi Mitre (b) (4)	08 Sep 2020 13:44:55

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	Xhoi Mitre (b) (4)	08 Sep 2020 13:44:55

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:54

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	Xhoi Mitre (b) (4)	08 Sep 2020 13:44:55

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:54

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4)	08 Sep 2020 13:44:55

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:54

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4)	08 Sep 2020 13:44:55

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:54

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'None (NONE)'	Xhoi Mitre (b) (4)	08 Sep 2020 13:44:55

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:54

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	Xhoi Mitre (b) (4)	08 Sep 2020 13:44:55

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:54

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User closed query 'Per CDM: Response noted, however the Indication for Conmed Zofran does not match the term for this AE. Please review and reconcile data.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 04:22:04
Query 'Per CDM: Response noted, however the Indication for Conmed Zofran does not match the term for this AE. Please review and reconcile data.' answered with 'updated' (Site from DM).	Monica Feeley (b) (4)	10 Nov 2020 22:03:45
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	(b) (4), (b) (6)	10 Nov 2020 10:27:08
' (Site from DM).		
User opened query 'Per CDM: Response noted, however the Indication for Conmed Zofran does not match the term for this AE. Please review and reconcile data.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 10:27:06
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	Monica Feeley (b) (4)	20 Oct 2020 16:04:58
' answered with 'please see zofran in con meds' (Site from DM).		
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	(b) (4), (b) (6)	02 Oct 2020 02:08:55
' (Site from DM).		
User entered 'I'	Xhoi Mitre (b) (4)	08 Sep 2020 13:44:55

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:54

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	Xhoi Mitre (b) (4)	08 Sep 2020 13:44:55

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:54

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Xhoi Mitre (b) (4)	08 Sep 2020 13:44:55

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:54

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Xhoi Mitre (b) (4)	08 Sep 2020 13:44:55

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:54

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:24
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Xhoi Mitre (b) (4)	08 Sep 2020 13:44:55

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:54

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:24
User entered '0'	System	08 Sep 2020 13:44:55

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:54

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:24
User entered '0'	System	08 Sep 2020 13:44:55

US3432229

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:35:54

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:20:24

US3432229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:54

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:27

US3432229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:54

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Oropharyngeal pain, LLT: Sore throat - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 21:15:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 21:15:44
Data point term sent to Coder	System	11 Sep 2020 21:14:36
User entered 'Sore Throat'	Xhoi Mitre (b) (4)	11 Sep 2020 21:13:57

US3432229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	Xhoi Mitre (b) (4)	11 Sep 2020 21:13:57

US3432229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:54

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	Xhoi Mitre (b) (4)	11 Sep 2020 21:13:57

US3432229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	Xhoi Mitre (b) (4)	11 Sep 2020 21:13:57

US3432229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '10 Sep 2020'	Xhoi Mitre (b) (4)	11 Sep 2020 21:13:57

US3432229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:54

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Xhoi Mitre (b) (4)	11 Sep 2020 21:13:57

US3432229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:54

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:27
User entered empty.	System	11 Sep 2020 21:13:57

US3432229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	Xhoi Mitre (b) (4)	11 Sep 2020 21:13:57

US3432229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:54

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '10 Sep 2020'	Xhoi Mitre (b) (4)	11 Sep 2020 21:13:57

US3432229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:54

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Xhoi Mitre (b) (4)	11 Sep 2020 21:13:57

US3432229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:54

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:27
User entered empty.	System	11 Sep 2020 21:13:57

US3432229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:54

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Grade 1/Mild (Grade 1/Mild)'	Xhoi Mitre (b) (4)	11 Sep 2020 21:13:57

US3432229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	Xhoi Mitre (b) (4)	11 Sep 2020 21:13:57

US3432229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:54

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	Xhoi Mitre (b) (4)	11 Sep 2020 21:13:57

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Folder: Adverse Events

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	Xhoi Mitre (b) (4)	11 Sep 2020 21:13:57

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	Xhoi Mitre (b) (4)	11 Sep 2020 21:13:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:54

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Xhoi Mitre (b) (4)	11 Sep 2020 21:13:57

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Folder: Adverse Events

Form: Adverse Events (2)

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Xhoi Mitre (b) (4)	11 Sep 2020 21:13:57

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Xhoi Mitre (b) (4)	11 Sep 2020 21:13:57

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Xhoi Mitre (b) (4)	11 Sep 2020 21:13:57

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Folder: Adverse Events

Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	Xhoi Mitre (b) (4)	11 Sep 2020 21:13:57

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	Xhoi Mitre (b) (4)	11 Sep 2020 21:13:57

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	Xhoi Mitre (b) (4)	11 Sep 2020 21:13:57

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4)	11 Sep 2020 21:13:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:54

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4)	11 Sep 2020 21:13:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:54

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'None (NONE)'	Xhoi Mitre (b) (4)	11 Sep 2020 21:13:57

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Folder: Adverse Events

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'I'	Xhoi Mitre (b) (4)	11 Sep 2020 21:13:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:54

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	Xhoi Mitre (b) (4)	11 Sep 2020 21:13:57

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	Xhoi Mitre (b) (4)	11 Sep 2020 21:13:57

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Folder: Adverse Events

Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Xhoi Mitre (b) (4)	11 Sep 2020 21:13:57

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Folder: Adverse Events

Form: Adverse Events (2)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Xhoi Mitre (b) (4)	11 Sep 2020 21:13:57

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:27
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Xhoi Mitre (b) (4)	11 Sep 2020 21:13:57

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:54

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:27
User entered '0'	System	11 Sep 2020 21:13:57

US3432229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:54

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:27
User entered '0'	System	11 Sep 2020 21:13:57

US3432229

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:35:54

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:42:27

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Folder: Adverse Events

Form: Adverse Events (3)

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[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:49:55
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:08:45
User entered	System	20 Oct 2020 19:08:39
'USA-US078-2020-mRNA-1273-P301000007'	(b) (4), (b) (6)	20 Oct 2020 19:08:39
User entered 'New'		

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Folder: Adverse Events

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[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:49:57
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User coded data point as SOC: Psychiatric disorders, HLT: Suicidal and self-injurious behaviour, PT: Intentional self-injury, LLT: Self injurious behavior - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 04:59:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 04:59:33
Data point term sent to Coder	System	20 Oct 2020 00:50:50
User entered 'Self- Injurious behavior'	Xhoi Mitre (b) (4)	20 Oct 2020 00:50:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:35:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:51:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	20 Oct 2020 00:50:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:35:54

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:51:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	Xhoi Mitre (b) (4)	20 Oct 2020 00:50:18

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:51:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	Xhoi Mitre (b) (4)	20 Oct 2020 00:50:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:51:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '17 Oct 2020'	Xhoi Mitre (b) (4)	20 Oct 2020 00:50:18

US3432229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:35:54

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:51:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Xhoi Mitre (b) (4)	20 Oct 2020 00:50:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:35:54

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 00:50:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:51:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)' reason for change: New Information	Monica Feeley (b) (4)	06 Nov 2020 13:24:53
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	20 Oct 2020 00:50:18

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Folder: Adverse Events

Form: Adverse Events (3)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:51:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 12:37:03
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety).	Monica Feeley (b) (4)	06 Nov 2020 13:25:07
User entered '30 Oct 2020' reason for change: New Information	Monica Feeley (b) (4)	06 Nov 2020 13:24:53
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 21:19:55
User entered empty.	Xhoi Mitre (b) (4)	20 Oct 2020 00:50:18

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Folder: Adverse Events

Form: Adverse Events (3)

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:51:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Xhoi Mitre (b) (4)	20 Oct 2020 00:50:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:35:54

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Oct 2020 00:50:18

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Folder: Adverse Events

Form: Adverse Events (3)

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:51:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User closed query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 12:37:09
Query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' answered with 'this is grade three as this was not life threatening' (Site from Safety).	Monica Feeley (b) (4)	06 Nov 2020 13:31:55
User opened query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 21:21:29
User entered 'Grade 3/Severe (Grade 3/Severe)'	Xhoi Mitre (b) (4)	20 Oct 2020 00:50:18

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:51:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	20 Oct 2020 00:50:18

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Folder: Adverse Events

Form: Adverse Events (3)

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:51:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	Xhoi Mitre (b) (4)	20 Oct 2020 00:50:18

US3432229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:35:54

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:51:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	Xhoi Mitre (b) (4)	20 Oct 2020 00:50:18

US3432229

Folder: Adverse Events

Form: Adverse Events (3)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:50:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	06 Nov 2020 08:18:45
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'currently hospitalized at time of data entry. admission date is provided' (Site from System).	Bruce Bausk (b) (4)	24 Oct 2020 13:26:11
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	24 Oct 2020 13:25:00
User entered '1' reason for change: Data Entry Error	Bruce Bausk (b) (4)	24 Oct 2020 13:25:00
User entered '0'	Xhoi Mitre (b) (4)	20 Oct 2020 00:50:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:35:54

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:51:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '24 Oct 2020' reason for change: New Information	Bruce Bausk (b) (4)	24 Oct 2020 13:25:00
User entered empty.	Xhoi Mitre (b) (4)	20 Oct 2020 00:50:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:35:54

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:50:31
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 12:37:15
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated' (Site from Safety).	Monica Feeley (b) (4)	06 Nov 2020 13:25:27
User entered '30 Oct 2020' reason for change: New Information	Monica Feeley (b) (4)	06 Nov 2020 13:24:53
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 21:19:37
User entered empty.	Xhoi Mitre (b) (4)	20 Oct 2020 00:50:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:35:54

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:51:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User closed query 'Per CDM: A response is needed for this field. Please update the field accordingly. Note: A response UNKNOWN can be recorded till the data is available.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 06:43:11
Query 'Per CDM: A response is needed for this field. Please update the field accordingly. Note: A response UNKNOWN can be recorded till the data is available.' answered with 'updated' (Site from DM).	Monica Feeley (b) (4)	06 Nov 2020 13:25:31
User entered 'No (N)' reason for change: New Information	Monica Feeley (b) (4)	06 Nov 2020 13:24:53
User opened query 'Per CDM: A response is needed for this field. Please update the field accordingly. Note: A response UNKNOWN can be recorded till the data is available.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 08:21:17
User entered empty.	Xhoi Mitre (b) (4)	20 Oct 2020 00:50:18

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:51:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Xhoi Mitre (b) (4)	20 Oct 2020 00:50:18

US3432229

Folder: Adverse Events

Form: Adverse Events (3)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:51:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	Xhoi Mitre (b) (4)	20 Oct 2020 00:50:18

US3432229

Folder: Adverse Events

Form: Adverse Events (3)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:51:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	Xhoi Mitre (b) (4)	20 Oct 2020 00:50:18

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:51:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'I'	Xhoi Mitre (b) (4)	20 Oct 2020 00:50:18

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:35:54

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:51:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4)	20 Oct 2020 00:50:18

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:51:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4)	20 Oct 2020 00:50:18

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Folder: Adverse Events

Form: Adverse Events (3)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:51:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Not Applicable (NOT APPLICABLE)'	Xhoi Mitre (b) (4)	20 Oct 2020 00:50:18

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Folder: Adverse Events

Form: Adverse Events (3)

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None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:51:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User closed query 'Per DM CLR: Please verify if treatments were given for this SAE as it required hospitalization and treatments may have been given. If treatments were given, please update to record accordingly. Otherwise, clarify reason why no treatment was needed.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 06:44:00
Query 'Per DM CLR: Please verify if treatments were given for this SAE as it required hospitalization and treatments may have been given. If treatments were given, please update to record accordingly. Otherwise, clarify reason why no treatment was needed.' answered with 'no treatments as of now. This is a psychological condition, treatments in the form of medication and procedures are not necessarily provided. Will update if anything changes' (Site from DM).	Monica Feeley (b) (4)	29 Oct 2020 13:51:17
User opened query 'Per DM CLR: Please verify if treatments were given for this SAE as it required hospitalization and treatments may have been given. If treatments were given, please update to record accordingly. Otherwise, clarify reason why no treatment was needed.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 23:03:29
User entered 'I'	Xhoi Mitre (b) (4)	20 Oct 2020 00:50:18

US3432229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:35:54

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:51:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	Xhoi Mitre (b) (4)	20 Oct 2020 00:50:18

US3432229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:35:54

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:51:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	Xhoi Mitre (b) (4)	20 Oct 2020 00:50:18

US3432229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:35:54

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:51:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 12:37:22
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Monica Feeley (b) (4)	06 Nov 2020 13:25:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Monica Feeley (b) (4)	06 Nov 2020 13:24:53
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 21:20:14
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Xhoi Mitre (b) (4)	20 Oct 2020 00:50:18

US3432229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:35:54

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:51:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Xhoi Mitre (b) (4)	20 Oct 2020 00:50:18

US3432229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:35:54

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:51:45
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 12:37:33
User closed query 'PV Query: Please assess if history of psychiatry hospitalization last in 2017 for suicidal ideation should be added to medical history.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 12:37:31
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 12:37:30
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Nov 2020 12:37:28
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'receiving repetitive transcranial magnetic stimulation (rTMS) daily starting 29OCT2020. Currently ongoing as outpatient.' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 13:38:33

US3432229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:35:54

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with '18OCT2020 COVID-19 NP swab- negative 23OCT2020 COVID-19 NP swab- negative ' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 13:36:09
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'no relevant laboratory results as this was a psychiatric admission ' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 13:31:07
Query 'PV Query: Please assess if history of psychiatry hospitalization last in 2017 for suicidal ideation should be added to medical history.' answered with 'already captured as medical history, see mood disorder' (Site from Safety).	Monica Feeley (b) (4) (b) (4)	06 Nov 2020 13:30:45
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 21:21:13
User opened query 'PV Query: Please assess if history of psychiatry hospitalization last in 2017 for suicidal ideation should be added to medical history.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 21:21:03
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 21:20:41
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	29 Oct 2020 21:20:28

US3432229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:35:54

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT PRESENTED TO THE ED ON 17OCT2020 FOR SELF-INJURIOUS BEHAVIOR. HAS HISTORY OF PSYCHIATRY HOSPITALIZATION (LAST IN 2017 FOR SUICIDAL IDEATION). CURRENT EPISODE IS THOUGHT TO BE AN EXACERBATION OF TRAUMA THEY EXPERIENCED. STAYED IN ED 17-18 OCT. AND WAS TRANSFERRED TO A COMMUNITY CRISIS STABILIZATION UNIT. TRIED TO CALL PARTICIPANT TODAY, NO ANSWER. WILL FOLLOW UP. 24Oct20 - Pt re-consulted in ED for self-injurious behavior. Symptomatology and assessment are similar to previous ED visit on 17Oct2020. Because of recent failure of CCS level of care, pt is hospitalized for current episode. Admitted this morning.' reason for change: New Information	Bruce Bausk (b) (4) (b) (4)	24 Oct 2020 13:25:00
User entered 'Participant presented to the ED on 17OCT2020 for self-injurious behavior. Has history of psychiatry hospitalization (last in 2017 for suicidal ideation). Current episode is thought to be an exacerbation of trauma they experienced. Stayed in ED 17-18 Oct. and was transferred to a community crisis stabilization unit. Tried to call participant today, No answer. Will follow up. '	Xhoi Mitre (b) (4) (b) (4)	20 Oct 2020 00:50:18

US3432229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:35:54

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	20 Oct 2020 00:50:18

US3432229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:35:54

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Oct 2020 00:50:18

US3432229

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:35:54

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	06 Nov 2020 13:24:53

US3432229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:35:54

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:04:54

US3432229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:35:54

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:04:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Eye and eyelid infections, PT: Hordeolum, LLT: Sty - version MedDRA\\23.0.	Coder Import (b) (4)	19 Jan 2021 22:06:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Jan 2021 22:06:11
Data point term sent to Coder	System	19 Jan 2021 22:05:10
User entered 'left eye sty'	Natalie Izaguirre (b) (4)	19 Jan 2021 22:04:12

US3432229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:35:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:04:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	19 Jan 2021 22:04:12

US3432229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:35:54

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:04:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	Natalie Izaguirre (b) (4)	19 Jan 2021 22:04:12

US3432229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:35:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:04:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	Natalie Izaguirre (b) (4)	19 Jan 2021 22:04:12

US3432229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:04:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '17 Jan 2021'	Natalie Izaguirre (b) (4)	19 Jan 2021 22:04:12

US3432229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:35:54

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:04:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Natalie Izaguirre (b) (4)	19 Jan 2021 22:04:12

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:35:54

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:04:54
User entered empty.	System	19 Jan 2021 22:04:12

US3432229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:04:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
Signature has been broken.	Tenaizus Woods (b) (4)	16 Apr 2021 17:55:34
User entered 'No (N)' reason for change: Data Entry Error	Tenaizus Woods (b) (4)	16 Apr 2021 17:55:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	19 Jan 2021 22:04:12

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:35:54

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:04:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
Signature has been broken.	Tenaizus Woods (b) (4)	16 Apr 2021 17:55:34
User entered '20 Jan 2021' reason for change: Data Entry Error	Tenaizus Woods (b) (4)	16 Apr 2021 17:55:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Natalie Izaguirre (b) (4)	19 Jan 2021 22:04:12

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:35:54

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:04:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Natalie Izaguirre (b) (4)	19 Jan 2021 22:04:12

US3432229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:35:54

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:04:54
User entered empty.	System	19 Jan 2021 22:04:12

US3432229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:35:54

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:04:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Grade 1/Mild (Grade 1/Mild)'	Natalie Izaguirre (b) (4)	19 Jan 2021 22:04:12

US3432229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:35:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:04:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	Natalie Izaguirre (b) (4)	19 Jan 2021 22:04:12

US3432229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:35:54

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:04:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	Natalie Izaguirre (b) (4)	19 Jan 2021 22:04:12

US3432229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:35:54

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:04:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	Natalie Izaguirre (b) (4)	19 Jan 2021 22:04:12

US3432229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:35:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:04:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	Natalie Izaguirre (b) (4)	19 Jan 2021 22:04:12

US3432229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:35:54

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:04:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Natalie Izaguirre (b) (4)	19 Jan 2021 22:04:12

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:35:54

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:04:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Natalie Izaguirre (b) (4)	19 Jan 2021 22:04:12

US3432229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:35:54

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:04:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Natalie Izaguirre (b) (4)	19 Jan 2021 22:04:12

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:35:54

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:04:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Natalie Izaguirre (b) (4)	19 Jan 2021 22:04:12

US3432229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:35:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:04:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	Natalie Izaguirre (b) (4)	19 Jan 2021 22:04:12

US3432229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:35:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:04:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	Natalie Izaguirre (b) (4)	19 Jan 2021 22:04:12

US3432229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:35:54

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:04:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	Natalie Izaguirre (b) (4)	19 Jan 2021 22:04:12

US3432229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:35:54

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:04:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Not Related (NOT RELATED)'	Natalie Izaguirre (b) (4)	19 Jan 2021 22:04:12

US3432229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:35:54

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:04:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Not Related (NOT RELATED)'	Natalie Izaguirre (b) (4)	19 Jan 2021 22:04:12

US3432229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:35:54

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:04:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Not Applicable (NOT APPLICABLE)'	Natalie Izaguirre (b) (4)	19 Jan 2021 22:04:12

US3432229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:35:54

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:04:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'I'	Natalie Izaguirre (b) (4)	19 Jan 2021 22:04:12

US3432229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:35:54

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:04:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	Natalie Izaguirre (b) (4)	19 Jan 2021 22:04:12

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:35:54

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:04:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	Natalie Izaguirre (b) (4)	19 Jan 2021 22:04:12

US3432229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:35:54

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:04:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
Signature has been broken.	Tenaizus Woods (b) (4)	16 Apr 2021 17:55:34
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Tenaizus Woods (b) (4)	16 Apr 2021 17:55:34
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Natalie Izaguirre (b) (4)	19 Jan 2021 22:04:12

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:35:54

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:04:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Natalie Izaguirre (b) (4)	19 Jan 2021 22:04:12

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:35:54

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:04:54
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Natalie Izaguirre (b) (4)	19 Jan 2021 22:04:12

US3432229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:35:54

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:04:54
User entered '0'	System	19 Jan 2021 22:04:12

US3432229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:35:54

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:04:54
User entered 'I'	System	19 Jan 2021 22:04:12

US3432229

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:35:54

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 06:04:54

US3432229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:35:54

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Spine and neck deformities, PT: Scoliosis, LLT: Scoliosis - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 12:53:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 12:53:56
Data point term sent to Coder	System	20 Apr 2021 12:53:22
User entered 'Mild Scoliosis'	Tenaizus Woods (b) (4)	20 Apr 2021 12:52:35
	(b) (4)	

US3432229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:35:54

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered 'No (N)'	Tenaizus Woods (b) (4) (b) (4)	20 Apr 2021 12:52:35

US3432229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:35:54

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered 'No (N)'	Tenaizus Woods (b) (4) (b) (4)	20 Apr 2021 12:52:35

US3432229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:35:54

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered 'No (N)'	Tenaizus Woods (b) (4) (b) (4)	20 Apr 2021 12:52:35

US3432229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered '02 Apr 2021'	Tenaizus Woods (b) (4) (b) (4)	20 Apr 2021 12:52:35

US3432229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:35:54

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered empty.	Tenaizus Woods (b) (4) (b) (4)	20 Apr 2021 12:52:35

US3432229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:35:54

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 12:52:35

US3432229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered 'Yes (Y)'	Tenaizus Woods (b) (4) (b) (4)	20 Apr 2021 12:52:35

US3432229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:35:54

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered empty.	Tenaizus Woods (b) (4) (b) (4)	20 Apr 2021 12:52:35

US3432229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:35:54

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered empty.	Tenaizus Woods (b) (4) (b) (4)	20 Apr 2021 12:52:35

US3432229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:35:54

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 12:52:35

US3432229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:35:54

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered 'Grade 1/Mild (Grade 1/Mild)'	Tenaizus Woods (b) (4) (b) (4)	20 Apr 2021 12:52:35

US3432229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:35:54

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered 'No (N)'	Tenaizus Woods (b) (4) (b) (4)	20 Apr 2021 12:52:35

US3432229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:35:54

Death

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered '0'	Tenaizus Woods (b) (4) (b) (4)	20 Apr 2021 12:52:35

US3432229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:35:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered '0'	Tenaizus Woods (b) (4) (b) (4)	20 Apr 2021 12:52:35

US3432229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:35:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered '0'	Tenaizus Woods (b) (4) (b) (4)	20 Apr 2021 12:52:35

US3432229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:35:54

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered empty.	Tenaizus Woods (b) (4) (b) (4)	20 Apr 2021 12:52:35

US3432229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:35:54

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered empty.	Tenaizus Woods (b) (4) (b) (4)	20 Apr 2021 12:52:35

US3432229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:35:54

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered empty.	Tenaizus Woods (b) (4) (b) (4)	20 Apr 2021 12:52:35

US3432229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:35:54

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered empty.	Tenaizus Woods (b) (4) (b) (4)	20 Apr 2021 12:52:35

US3432229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:35:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered '0'	Tenaizus Woods (b) (4) (b) (4)	20 Apr 2021 12:52:35

US3432229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:35:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered '0'	Tenaizus Woods (b) (4) (b) (4)	20 Apr 2021 12:52:35

US3432229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:35:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered '0'	Tenaizus Woods (b) (4) (b) (4)	20 Apr 2021 12:52:35

US3432229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:35:54

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered 'Not Related (NOT RELATED)'	Tenaizus Woods (b) (4) (b) (4)	20 Apr 2021 12:52:35

US3432229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:35:54

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered 'Not Related (NOT RELATED)'	Tenaizus Woods (b) (4) (b) (4)	20 Apr 2021 12:52:35

US3432229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:35:54

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered 'Not Applicable (NOT APPLICABLE)'	Tenaizus Woods (b) (4) (b) (4)	20 Apr 2021 12:52:35

US3432229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:35:54

None

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered '1'	Tenaizus Woods (b) (4) (b) (4)	20 Apr 2021 12:52:35

US3432229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:35:54

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered '0'	Tenaizus Woods (b) (4) (b) (4)	20 Apr 2021 12:52:35

US3432229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:35:54

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered '0'	Tenaizus Woods (b) (4) (b) (4)	20 Apr 2021 12:52:35

US3432229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:35:54

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Tenaizus Woods (b) (4)	20 Apr 2021 12:52:35
	(b) (4)	

US3432229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:35:54

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered empty.	Tenaizus Woods (b) (4) (b) (4)	20 Apr 2021 12:52:35

US3432229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:35:54

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:08:31
User entered empty.	Tenaizus Woods (b) (4) (b) (4)	20 Apr 2021 12:52:35

US3432229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:35:54

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Apr 2021 12:52:35

US3432229

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:35:54

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Apr 2021 12:52:35

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:35:54

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:53:12
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:42:10
User closed query 'Per DM CLR: Per Diary Dose 2 Day 1 Pain at Injection Site; Day 6 Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 08:54:19
Query 'Per DM CLR: Per Diary Dose 2 Day 1 Pain at Injection Site; Day 6 Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'As stated in the quoted response "Repeated use of over-the-counter pain reliever > 24 hours OR some interference with activity," the "or" clause means that the condition merely needs to interfere with activity and as noted in the e-diary participant did NOT take medication. ' (Site from DM).	Phoebe Cunningham (b) (4)	18 Mar 2021 16:06:36
User opened query 'Per DM CLR: Per Diary Dose 2 Day 1 Pain at Injection Site; Day 6 Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 02:53:56
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	21 Aug 2020 22:10:41

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: LISDEXAMFETAMINE MESILATE, PRODUCTSYNONYM: VYVANSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 22:13:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 22:13:22
Data point term sent to Coder	System	21 Aug 2020 22:12:41
User entered 'vyvanse'	Xhoi Mitre (b) (4)	21 Aug 2020 22:12:03
	(b) (4)	

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	Xhoi Mitre (b) (4)	21 Aug 2020 22:12:03
	(b) (4)	

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'ADHD'	Xhoi Mitre (b) (4)	21 Aug 2020 22:12:03
	(b) (4)	

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '40'	Xhoi Mitre (b) (4)	21 Aug 2020 22:12:03
	(b) (4)	

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'mg (mg)'	Xhoi Mitre (b) (4)	21 Aug 2020 22:12:03
	(b) (4)	

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:54

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 02:05:28
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	21 Aug 2020 22:12:03

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'once daily (QD)'	Xhoi Mitre (b) (4)	21 Aug 2020 22:12:03
	(b) (4)	

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 02:05:28
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	21 Aug 2020 22:12:03

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Oral (ORAL)'	Xhoi Mitre (b) (4)	21 Aug 2020 22:12:03
	(b) (4)	

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 02:05:28
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	21 Aug 2020 22:12:03

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:54

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'UN UNK 2016'	Xhoi Mitre (b) (4)	21 Aug 2020 22:12:03
	(b) (4)	

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 02:05:28
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	21 Aug 2020 22:12:03

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	21 Aug 2020 22:12:03
	(b) (4)	

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 02:05:28
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	21 Aug 2020 22:12:03

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	Xhoi Mitre (b) (4)	21 Aug 2020 22:12:03
	(b) (4)	

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 22:12:03

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 22:12:03

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:35:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 22:12:03

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
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)	23 Aug 2020 19:18:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Aug 2020 19:18:42
Data point term sent to Coder	System	21 Aug 2020 22:13:43
User entered 'Wellbutrin'	Xhoi Mitre (b) (4)	21 Aug 2020 22:12:53

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	Xhoi Mitre (b) (4)	21 Aug 2020 22:12:53
	(b) (4)	

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:35:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 02:05:28
User entered 'Mood Disorder'	Xhoi Mitre (b) (4) (b) (4)	21 Aug 2020 22:12:53

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '450'	Xhoi Mitre (b) (4)	21 Aug 2020 22:12:53
	(b) (4)	

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:35:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'mg (mg)'	Xhoi Mitre (b) (4)	21 Aug 2020 22:12:53
	(b) (4)	

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:35:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Xhoi Mitre (b) (4)	21 Aug 2020 22:12:53
	(b) (4)	

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:35:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'once daily (QD)'	Xhoi Mitre (b) (4)	21 Aug 2020 22:12:53
	(b) (4)	

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:35:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 02:05:28
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	21 Aug 2020 22:12:53

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:35:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Oral (ORAL)'	Xhoi Mitre (b) (4)	21 Aug 2020 22:12:53
	(b) (4)	

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:35:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Xhoi Mitre (b) (4)	21 Aug 2020 22:12:53
	(b) (4)	

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'UN Feb 2020'	Xhoi Mitre (b) (4)	21 Aug 2020 22:12:53
	(b) (4)	

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 02:05:28
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	21 Aug 2020 22:12:53

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 02:05:28
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	21 Aug 2020 22:12:53

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:35:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 02:05:28
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	21 Aug 2020 22:12:53

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	Xhoi Mitre (b) (4)	21 Aug 2020 22:12:53
	(b) (4)	

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:35:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 22:12:53

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:35:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 22:12:53

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:35:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 22:12:53

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: BUDESONIDE;FORMOTEROL FUMARATE, PRODUCTSYNONYM: SYMBICORT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 22:19:29
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 22:19:29
Data point term sent to Coder	System	21 Aug 2020 22:18:50
User entered 'Symbicort'	(b) (4), (b) (6)	21 Aug 2020 22:18:13

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 22:18:13

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:35:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Asthma'	(b) (4), (b) (6)	21 Aug 2020 22:18:13

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User closed query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of puff/s. Please verify the dose and unit, and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 07:43:38
Query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of puff/s. Please verify the dose and unit, and update as appropriate. ' answered with 'unknown. this is what participant provided' (Site from DM).	Monica Feeley (b) (4)	10 Nov 2020 21:46:26
User opened query 'Per DM CLR: Please update the DOSE and UNIT entries for this combination drug to list the specific doses for each component rather than a number of puff/s. Please verify the dose and unit, and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 06:19:06
User entered '2'	(b) (4), (b) (6)	21 Aug 2020 22:18:13

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:35:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'puff (PUFF)'	(b) (4), (b) (6)	21 Aug 2020 22:18:13

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:35:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 22:18:13

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:35:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'twice daily (BID)'	(b) (4), (b) (6)	21 Aug 2020 22:18:13

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:35:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 22:18:13

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:35:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	21 Aug 2020 22:18:13

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:35:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 22:18:13

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:35:54

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'un Feb 2020'	(b) (4), (b) (6)	21 Aug 2020 22:18:13

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 22:18:13

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 22:18:13

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:35:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 22:18:13

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 22:18:13

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:35:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	21 Aug 2020 22:18:13

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:35:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 22:18:13

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:35:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 22:18:13

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, INHALANTS, ATC: GLUCOCORTICOIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLOVENT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 22:21:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 22:21:16
Data point term sent to Coder	System	21 Aug 2020 22:20:55
User entered 'Flovent'	(b) (4), (b) (6)	21 Aug 2020 22:20:26

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 22:20:26

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:35:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Asthma'	(b) (4), (b) (6)	21 Aug 2020 22:20:26

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MG, etc) instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 07:43:45
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MG, etc) instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' answered with 'unknown. This is information that participant provided' (Site from DM).	Monica Feeley (b) (4)	10 Nov 2020 21:50:35
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 50 MCG, 100 MG, etc) instead of puff count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 06:21:03
User entered '2'	(b) (4), (b) (6)	21 Aug 2020 22:20:26

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:35:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'puff (PUFF)'	(b) (4), (b) (6)	21 Aug 2020 22:20:26

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:35:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 22:20:26

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:35:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'twice daily (BID)'	(b) (4), (b) (6)	21 Aug 2020 22:20:26

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:35:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 22:20:26

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:35:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	21 Aug 2020 22:20:26

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:35:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 22:20:26

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'un Jun 2019'	(b) (4), (b) (6)	21 Aug 2020 22:20:26

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 22:20:26

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 22:20:26

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:35:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'un Jun 2020'	(b) (4), (b) (6)	21 Aug 2020 22:20:26

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 22:20:26

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:35:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:49
User entered '2'	System	21 Aug 2020 22:20:26

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:35:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:49
User entered '1'	System	21 Aug 2020 22:20:26

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:35:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:49
User entered '804 (804)'	System	21 Aug 2020 22:20:26

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
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)	21 Aug 2020 22:23:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 22:23:18
Data point term sent to Coder	System	21 Aug 2020 22:22:57
User entered 'Albuterol'	(b) (4), (b) (6)	21 Aug 2020 22:22:27

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 22:22:27

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:35:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Asthma'	(b) (4), (b) (6)	21 Aug 2020 22:22:27

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '2'	(b) (4), (b) (6)	21 Aug 2020 22:22:27

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:35:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'puff (PUFF)'	(b) (4), (b) (6)	21 Aug 2020 22:22:27

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:35:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 22:22:27

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:35:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'as needed (PRN)'	(b) (4), (b) (6)	21 Aug 2020 22:22:27

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:35:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 22:22:27

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:35:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	(b) (4), (b) (6)	21 Aug 2020 22:22:27

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:35:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 22:22:27

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '21 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 22:22:27

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 22:22:27

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 22:22:27

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:35:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 22:22:27

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 22:22:27

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:35:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 22:22:27

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:35:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 22:22:27

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:35:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 22:22:27

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ANDROGENS, ATC: 3-OXOANDROSTEN (4) DERIVATIVES, PRODUCT: TESTOSTERONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 04:44:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 04:44:32
Data point term sent to Coder	System	21 Aug 2020 22:23:58
User entered 'Testosterone'	(b) (4), (b) (6)	21 Aug 2020 22:23:57

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
	(b) (4), (b) (6)	29 Jan 2021 05:47:02
User closed query 'Per DM CLR: Per indication below, review if this should be updated to YES if used as prophylaxis. Update or provide further clarification.' (Site from DM).	Alexander Mills (b) (4)	28 Jan 2021 14:09:46
Query 'Per DM CLR: Per indication below, review if this should be updated to YES if used as prophylaxis. Update or provide further clarification.' answered with 'updated' (Site from DM).	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Alexander Mills (b) (4)	28 Jan 2021 14:09:38
User opened query 'Per DM CLR: Per indication below, review if this should be updated to YES if used as prophylaxis. Update or provide further clarification.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 04:39:51
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 22:23:57

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:35:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
	(b) (4), (b) (6)	30 Nov 2020 04:38:45
User closed query 'Per DM CLR: Please update INDICATION to include the actual medical condition the med is being used to prevent/treat. Please review and update accordingly. (Site from DM).		
Query 'Per DM CLR: Please update INDICATION to include the actual medical condition the med is being used to prevent/treat. Please review and update accordingly.	Monica Feeley (b) (4)	20 Oct 2020 16:06:02
' answered with 'used by participant for "general health" purposes' (Site from DM).		
User opened query 'Per DM CLR: Please update INDICATION to include the actual medical condition the med is being used to prevent/treat. Please review and update accordingly. (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 09:11:56
User entered 'general health'	(b) (4), (b) (6)	21 Aug 2020 22:23:57

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '40'	(b) (4), (b) (6)	21 Aug 2020 22:23:57

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:35:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Aug 2020 22:23:57

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:35:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 22:23:57

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:35:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'other (OTHER)'	(b) (4), (b) (6)	21 Aug 2020 22:23:57

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:35:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'once every 9 weeks'	(b) (4), (b) (6)	21 Aug 2020 22:23:57

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:35:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	21 Aug 2020 22:23:57

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:35:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 22:23:57

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'un Nov 2019'	(b) (4), (b) (6)	21 Aug 2020 22:23:57

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 22:23:57

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 22:23:57

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:35:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 22:23:57

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 22:23:57

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:35:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 22:23:57

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:35:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 22:23:57

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:35:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 22:23:57

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:02
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Sep 2020 22:02:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Sep 2020 22:02:36
Data point term sent to Coder	System	05 Sep 2020 14:21:43
User entered 'Meloxicam'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:20:45

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:02
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:20:45

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:35:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:02
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Menstrual cramps'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:20:45

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:02
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 10:13:38
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'dosage reported by participant' (Site from DM).	Monica Feeley (b) (4)	20 Oct 2020 16:06:31
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 06:15:33
User entered '14'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:20:45

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:35:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:02
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'mg (mg)'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:20:45

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:35:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:02
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Phoebe Cunningham (b) (4)	05 Sep 2020 14:20:45

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:35:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:02
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'once daily (QD)'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:20:45

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:35:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:02
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Phoebe Cunningham (b) (4)	05 Sep 2020 14:20:45

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:35:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:02
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Oral (ORAL)'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:20:45

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:35:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:02
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Phoebe Cunningham (b) (4)	05 Sep 2020 14:20:45

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:02
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '22 Aug 2020'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:20:45

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:02
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:20:45

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:02
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:20:45

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:35:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:02
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '23 Aug 2020'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:20:45

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:02
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:20:45

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:35:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:02
User entered '1'	System	05 Sep 2020 14:20:45

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:35:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:02
User entered '1'	System	05 Sep 2020 14:20:45

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:35:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:02
User entered '804 (804)'	System	05 Sep 2020 14:20:45

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Sep 2020 22:03:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Sep 2020 22:03:36
Data point term sent to Coder	System	05 Sep 2020 14:22:44
User entered 'Meloxicam'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:22:43

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:22:43

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:35:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
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 HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 08:26:02
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' answered with 'no ae needed' (Site from DM).	Monica Feeley (b) (4)	20 Oct 2020 16:06:53

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 09 Jun 2021 17:35:54

[illegible]

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 10:15:19
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'dosage reported by participant' (Site from DM).	Monica Feeley (b) (4)	20 Oct 2020 16:07:31
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 06:16:10
User entered '14'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:22:43

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:35:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'mg (mg)'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:22:43

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:35:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Phoebe Cunningham (b) (4)	05 Sep 2020 14:22:43

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:35:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'once daily (QD)'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:22:43

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:35:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Phoebe Cunningham (b) (4)	05 Sep 2020 14:22:43

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:35:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Oral (ORAL)'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:22:43

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:35:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Phoebe Cunningham (b) (4)	05 Sep 2020 14:22:43

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User closed query 'Per DM CLR: Please review Start date of this medication as this is after the occurrence of Headache which started 26 Aug 2020 per Diary. Either update CM start date or confirm in query response that CM was given during this recorded date.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 07:44:12
Query 'Per DM CLR: Please review Start date of this medication as this is after the occurrence of Headache which started 26 Aug 2020 per Diary. Either update CM start date or confirm in query response that CM was given during this recorded date.' answered with 'headache occurred on 27AUG2020 as per diary?' (Site from DM).	Monica Feeley (b) (4)	10 Nov 2020 21:51:54
User opened query 'Per DM CLR: Please review Start date of this medication as this is after the occurrence of Headache which started 26 Aug 2020 per Diary. Either update CM start date or confirm in query response that CM was given during this recorded date.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 07:48:33
User entered '27 Aug 2020'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:22:43

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:22:43

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:22:43

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:35:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '27 Aug 2020'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:22:43

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:09
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:22:43

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:35:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:09
User entered '1'	System	05 Sep 2020 14:22:43

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:35:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:09
User entered '1'	System	05 Sep 2020 14:22:43

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:35:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:09
User entered '804 (804)'	System	05 Sep 2020 14:22:43

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Sep 2020 22:03:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Sep 2020 22:03:36
Data point term sent to Coder	System	05 Sep 2020 14:26:49
User entered 'Meloxicam'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:26:14

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:26:14

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:35:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User closed query 'Per DM CLR: Please note there is no MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH/ AE eCRF.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 10:22:51
Query 'Per DM CLR: Please note there is no MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH/ AE eCRF.' answered with 'no AE' (Site from DM).	Monica Feeley (b) (4)	20 Oct 2020 16:07:41
User opened query 'Per DM CLR: Please note there is no MH condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate MH/ AE eCRF.' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 06:16:42
User entered 'headache'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:26:14

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 10:28:51
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'dosage reported by participant' (Site from DM).	Monica Feeley (b) (4)	20 Oct 2020 16:07:45
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 06:16:38
User entered '14'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:26:14

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:35:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'mg (mg)'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:26:14

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:35:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Phoebe Cunningham (b) (4)	05 Sep 2020 14:26:14

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:35:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'once (ONCE)'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:26:14

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:35:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Phoebe Cunningham (b) (4)	05 Sep 2020 14:26:14

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:35:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Oral (ORAL)'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:26:14

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:35:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Phoebe Cunningham (b) (4)	05 Sep 2020 14:26:14

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '28 Aug 2020'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:26:14

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:26:14

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:26:14

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:35:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '28 Aug 2020'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:26:14

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	Phoebe Cunningham (b) (4)	05 Sep 2020 14:26:14

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:35:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:16
User entered empty.	System	05 Sep 2020 14:26:14

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:35:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:16
User entered empty.	System	05 Sep 2020 14:26:14

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:35:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:16
User entered empty.	System	05 Sep 2020 14:26:14

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: SODIUM, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Sep 2020 09:09:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Sep 2020 09:09:53
Data point term sent to Coder	System	18 Sep 2020 16:15:33
User entered 'Sodium chloride'	Bruce Bausk (b) (4)	18 Sep 2020 16:14:34

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	Bruce Bausk (b) (4)	18 Sep 2020 16:14:34
	(b) (4)	

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:35:54

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'orthostatic pre-syncope'	Bruce Bausk (b) (4)	18 Sep 2020 16:14:34
	(b) (4)	

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '1'	Bruce Bausk (b) (4)	18 Sep 2020 16:14:34
	(b) (4)	

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:35:54

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'g (g)'	Bruce Bausk (b) (4)	18 Sep 2020 16:14:34
	(b) (4)	

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:35:54

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Bruce Bausk (b) (4)	18 Sep 2020 16:14:34
	(b) (4)	

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:35:54

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'once daily (QD)'	Bruce Bausk (b) (4)	18 Sep 2020 16:14:34
	(b) (4)	

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:35:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 02:05:28
User entered empty.	Bruce Bausk (b) (4) (b) (4)	18 Sep 2020 16:14:34

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:35:54

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 02:05:28
User entered 'Oral (ORAL)'	Bruce Bausk (b) (4) (b) (4)	18 Sep 2020 16:14:34

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:35:54

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Bruce Bausk (b) (4)	18 Sep 2020 16:14:34
	(b) (4)	

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:35:54

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '25 Aug 2020'	Bruce Bausk (b) (4)	18 Sep 2020 16:14:34
	(b) (4)	

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:35:54

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	Bruce Bausk (b) (4)	18 Sep 2020 16:14:34
	(b) (4)	

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 02:05:28
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	18 Sep 2020 16:14:34

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:35:54

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 02:05:28
User entered empty.	Bruce Bausk (b) (4) (b) (4)	18 Sep 2020 16:14:34

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	Bruce Bausk (b) (4)	18 Sep 2020 16:14:34
	(b) (4)	

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:35:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 16:14:34

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:35:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 16:14:34

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:35:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Sep 2020 16:14:34

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
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)	25 Sep 2020 20:10:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Sep 2020 20:10:49
Data point term sent to Coder	System	25 Sep 2020 20:10:14
User entered 'Tylenol'	(b) (4), (b) (6)	25 Sep 2020 20:09:43

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 20:09:43

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:35:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
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, PAIN AT INJECTION SITE, MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHES, PAIN AT INJECTION SITE, MUSCLE ACHES did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 07:45:47
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHES, PAIN AT INJECTION SITE, MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHES, PAIN AT INJECTION SITE, MUSCLE ACHES did not meet the AE reporting criteria. ' answered with 'no AE' (Site from DM).	Monica Feeley (b) (4)	10 Nov 2020 21:52:09

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:35:54

[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, PAIN AT INJECTION SITE, MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHES, PAIN AT INJECTION SITE, MUSCLE ACHES did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 07:32:12
User entered 'Headaches, pain at injection site, muscle aches'	(b) (4), (b) (6)	25 Sep 2020 20:09:43

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '1000'	(b) (4), (b) (6)	25 Sep 2020 20:09:43

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:35:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Sep 2020 20:09:43

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:35:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 20:09:43

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:35:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'three times daily (TID)'	(b) (4), (b) (6)	25 Sep 2020 20:09:43

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:35:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 20:09:43

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:35:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Sep 2020 20:09:43

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:35:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 20:09:43

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '19 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 20:09:43

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 20:09:43

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 20:09:43

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:35:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '20 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 20:09:43

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 20:09:43

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:35:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:40
User entered '3'	System	25 Sep 2020 20:09:43

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:35:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:40
User entered '1'	System	25 Sep 2020 20:09:43

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:35:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:40
User entered '804 (804)'	System	25 Sep 2020 20:09:43

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 09:35:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 09:35:34
Data point term sent to Coder	System	25 Sep 2020 20:13:28
User entered 'Ibuprofen'	(b) (4), (b) (6)	25 Sep 2020 20:12:34

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 20:12:34

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:35:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
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, PAIN AT INJECTION SITE, MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHES, PAIN AT INJECTION SITE, MUSCLE ACHES did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 07:45:53
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHES, PAIN AT INJECTION SITE, MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHES, PAIN AT INJECTION SITE, MUSCLE ACHES did not meet the AE reporting criteria. ' answered with 'no AE' (Site from DM).	Monica Feeley (b) (4)	10 Nov 2020 21:52:18

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:35:54

[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, PAIN AT INJECTION SITE, MUSCLE ACHES is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHES, PAIN AT INJECTION SITE, MUSCLE ACHES did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 07:59:05
User entered 'Headaches, pain at injection site, muscle aches.'	(b) (4), (b) (6)	25 Sep 2020 20:12:34

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '600'	(b) (4), (b) (6)	25 Sep 2020 20:12:34

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:35:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Sep 2020 20:12:34

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:35:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 20:12:34

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:35:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'three times daily (TID)'	(b) (4), (b) (6)	25 Sep 2020 20:12:34

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:35:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 20:12:34

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:35:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	25 Sep 2020 20:12:34

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:35:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	(b) (4), (b) (6)	25 Sep 2020 20:12:34

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '19 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 20:12:34

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	(b) (4), (b) (6)	25 Sep 2020 20:12:34

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	(b) (4), (b) (6)	25 Sep 2020 20:12:34

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:35:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '20 Sep 2020'	(b) (4), (b) (6)	25 Sep 2020 20:12:34

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:29
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Sep 2020 20:12:34

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:35:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:29
User entered '3'	System	25 Sep 2020 20:12:34

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:35:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:29
User entered '1'	System	25 Sep 2020 20:12:34

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:35:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:35:29
User entered '804 (804)'	System	25 Sep 2020 20:12:34

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 04:41:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 04:41:48
Data point term sent to Coder Coding entries removed.	System Monica Feeley (b) (4)	10 Nov 2020 22:04:58 10 Nov 2020 22:04:09
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 15:26:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 15:26:27
Data point term sent to Coder User entered 'Zofran'	System Xhoi Mitre (b) (4)	06 Oct 2020 14:56:16 06 Oct 2020 14:55:28

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	Xhoi Mitre (b) (4)	06 Oct 2020 14:55:28

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:35:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'transient gastrointestinal illness' reason for change: Per Query Resolution	Monica Feeley (b) (4)	10 Nov 2020 22:04:09
User entered 'Nausea/ vomiting'	Xhoi Mitre (b) (4)	06 Oct 2020 14:55:28

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '4'	Xhoi Mitre (b) (4)	06 Oct 2020 14:55:28

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:35:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'mg (mg)'	Xhoi Mitre (b) (4)	06 Oct 2020 14:55:28

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:35:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Xhoi Mitre (b) (4)	06 Oct 2020 14:55:28

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:35:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'once (ONCE)'	Xhoi Mitre (b) (4)	06 Oct 2020 14:55:28

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:35:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Xhoi Mitre (b) (4)	06 Oct 2020 14:55:28

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:35:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Oral (ORAL)'	Xhoi Mitre (b) (4)	06 Oct 2020 14:55:28

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:35:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	Xhoi Mitre (b) (4)	06 Oct 2020 14:55:28

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '04 Sep 2020'	Xhoi Mitre (b) (4)	06 Oct 2020 14:55:28

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '0'	Xhoi Mitre (b) (4)	06 Oct 2020 14:55:28

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	Xhoi Mitre (b) (4)	06 Oct 2020 14:55:28

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:35:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '04 Sep 2020'	Xhoi Mitre (b) (4)	06 Oct 2020 14:55:28

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:16
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'No (N)'	Xhoi Mitre (b) (4)	06 Oct 2020 14:55:28

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:35:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:16
User entered empty.	System	06 Oct 2020 14:55:28

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:35:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:16
User entered empty.	System	06 Oct 2020 14:55:28

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:35:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:16
User entered empty.	System	06 Oct 2020 14:55:28

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:35:54

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:01
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
User closed query 'Per DM CLR: Con Med ABILIFY was added/changed on 24 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 08:30:12
Query 'Per DM CLR: Con Med ABILIFY was added/changed on 24 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'no worsening, just adjustment of medication' (Site from DM).	Monica Feeley (b) (4)	07 Apr 2021 21:38:53
User opened query 'Per DM CLR: Con Med ABILIFY was added/changed on 24 OCT 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 06:34:11
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 19:00:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: ARIPIRAZOLE, PRODUCTSYNONYM: ABILIFY - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Mar 2021 17:35:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Mar 2021 17:35:08
Data point term sent to Coder	System	04 Mar 2021 17:34:51
User entered 'Abilify'	Monica Feeley (b) (4)	04 Mar 2021 17:34:37

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:01
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 19:00:43
User entered 'No (N)'	Monica Feeley (b) (4)	04 Mar 2021 17:34:37

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:35:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:01
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 19:00:43
User entered 'Mood disorder'	Monica Feeley (b) (4)	04 Mar 2021 17:34:37

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:01
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 19:00:43
User entered '7.5'	Monica Feeley (b) (4)	04 Mar 2021 17:34:37

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:35:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:01
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 19:00:43
User entered 'mg (mg)'	Monica Feeley (b) (4)	04 Mar 2021 17:34:37

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:35:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:01
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 19:00:43
User entered empty.	Monica Feeley (b) (4)	04 Mar 2021 17:34:37

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:35:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:01
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 19:00:43
User entered 'once daily (QD)'	Monica Feeley (b) (4)	04 Mar 2021 17:34:37

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:35:54

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:01
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 19:00:43
User entered empty.	Monica Feeley (b) (4)	04 Mar 2021 17:34:37

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:35:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:01
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 19:00:43
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	04 Mar 2021 17:34:37

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:35:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:01
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 19:00:43
User entered empty.	Monica Feeley (b) (4)	04 Mar 2021 17:34:37

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:01
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 19:00:43
User entered '24 Oct 2020'	Monica Feeley (b) (4)	04 Mar 2021 17:34:37

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:01
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 19:00:43
User entered '0'	Monica Feeley (b) (4)	04 Mar 2021 17:34:37

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:01
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 19:00:43
User entered 'No (N)'	Monica Feeley (b) (4)	04 Mar 2021 17:34:37

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:35:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:01
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 19:00:43
User entered '26 Oct 2020'	Monica Feeley (b) (4)	04 Mar 2021 17:34:37

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:01
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 19:00:43
User entered 'No (N)'	Monica Feeley (b) (4)	04 Mar 2021 17:34:37

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:35:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:01
User entered '1'	System	04 Mar 2021 17:34:37

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:35:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:01
User entered '1'	System	04 Mar 2021 17:34:37

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:35:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:01
User entered '804 (804)'	System	04 Mar 2021 17:34:37

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
User closed query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 08:30:34
Query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation. ' answered with 'no worsening. just adjustment of medication ' (Site from DM).	Monica Feeley (b) (4)	07 Apr 2021 21:38:35
User opened query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 06:34:41
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 19:00:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: ARIPIPIRAZOLE, PRODUCTSYNONYM: ABILIFY - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Mar 2021 17:37:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Mar 2021 17:37:01
Data point term sent to Coder	System	04 Mar 2021 17:35:53

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:35:54

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Abilify'	Monica Feeley (b) (4) (b) (4)	04 Mar 2021 17:35:06

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:35:54

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
Un-reviewed for Data Management.	(b) (4), (b) (6)	30 Mar 2021 06:34:24
Reviewed for Data Management.	(b) (4), (b) (6)	30 Mar 2021 06:34:21
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 19:00:45
User entered 'No (N)'	Monica Feeley (b) (4)	04 Mar 2021 17:35:06

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:35:54

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 19:00:45
User entered 'Mood disorder'	Monica Feeley (b) (4)	04 Mar 2021 17:35:06

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:35:54

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 19:00:45
User entered '10'	Monica Feeley (b) (4)	04 Mar 2021 17:35:06

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:35:54

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 19:00:45
User entered 'mg (mg)'	Monica Feeley (b) (4)	04 Mar 2021 17:35:06

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:35:54

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 19:00:45
User entered empty.	Monica Feeley (b) (4)	04 Mar 2021 17:35:06

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:35:54

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 19:00:45
User entered 'once daily (QD)'	Monica Feeley (b) (4)	04 Mar 2021 17:35:06

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:35:54

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 19:00:45
User entered empty.	Monica Feeley (b) (4)	04 Mar 2021 17:35:06

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:35:54

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 19:00:45
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	04 Mar 2021 17:35:06

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:35:54

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 19:00:45
User entered empty.	Monica Feeley (b) (4)	04 Mar 2021 17:35:06

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:35:54

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 19:00:45
User entered '27 Oct 2020'	Monica Feeley (b) (4)	04 Mar 2021 17:35:06

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:35:54

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 19:00:45
User entered '0'	Monica Feeley (b) (4)	04 Mar 2021 17:35:06

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:35:54

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 19:00:45
User entered 'No (N)'	Monica Feeley (b) (4)	04 Mar 2021 17:35:06

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:35:54

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 19:00:45
User entered '14 Nov 2020'	Monica Feeley (b) (4)	04 Mar 2021 17:35:06

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:35:54

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:08
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:08:31
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 19:00:45
User entered 'No (N)'	Monica Feeley (b) (4)	04 Mar 2021 17:35:06

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:35:54

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:08
User entered '1'	System	04 Mar 2021 17:35:06

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:35:54

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:08
User entered '1'	System	04 Mar 2021 17:35:06

US3432229

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:35:54

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:36:08
User entered '804 (804)'	System	04 Mar 2021 17:35:06

US3432229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:35:54

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:53:12
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	10 Oct 2020 18:16:28
User entered 'No (N)' reason for change: Data Entry Error	Xhoi Mitre (b) (4)	21 Aug 2020 22:10:35
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	21 Aug 2020 22:10:14

US3432229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:35:54

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:49:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '2 Oct 2020'	(b) (4), (b) (6)	10 Oct 2020 18:16:43

US3432229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:35:54

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:49:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'RTMS (Transcranial magnetic stimulation)' reason for change: Data Entry Error	Bruce Bausk (b) (4)	10 Oct 2020 18:19:04
User entered 'RTMS'	(b) (4), (b) (6)	10 Oct 2020 18:16:43

US3432229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:35:54

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:49:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered 'Medical History (MH)'	(b) (4), (b) (6)	10 Oct 2020 18:16:43

US3432229

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:35:54

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:49:40
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered empty.	(b) (4), (b) (6)	10 Oct 2020 18:16:43

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered	System	20 Oct 2020 19:08:39
'USA-US078-2020-MRNA-1273-P301000007'		

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'Yes (Y)'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'No (N)'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'No (N)'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:01:02
Un-reviewed for Safety.	System	24 Oct 2020 13:25:00
User entered 'Yes (Y)'	System	24 Oct 2020 13:25:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'No (N)'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'No (N)'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'No (N)'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'Yes (Y)'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'Lindsey'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'Baden'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'MA'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:22
User entered 'US'	System	20 Oct 2020 19:09:15

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '3'	System	09 Nov 2020 12:37:51
User entered '2'	System	26 Oct 2020 16:01:13
User entered '1'	System	20 Oct 2020 19:09:15

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered	System	20 Oct 2020 19:08:39
'USA-US078-2020-MRNA-1273-P301000007'		

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'Yes (Y)'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'No (N)'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'No (N)'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:01:02
Un-reviewed for Safety.	System	24 Oct 2020 13:25:00
User entered 'Yes (Y)'	System	24 Oct 2020 13:25:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'No (N)'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'No (N)'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'No (N)'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'Yes (Y)'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'Lindsey'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'Baden'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'MA'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:22
User entered 'US'	System	20 Oct 2020 19:09:15

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '3'	System	09 Nov 2020 12:37:51
User entered '2'	System	26 Oct 2020 16:01:13
User entered '1'	System	20 Oct 2020 19:09:15

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:35:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
User entered '20/Oct/2020 19:09'	System	20 Oct 2020 19:09:15

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:35:54

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:22
User entered 'I'	(b) (4), (b) (6)	20 Oct 2020 19:09:15

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered	System	20 Oct 2020 19:08:39
'USA-US078-2020-MRNA-1273-P301000007'		

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'Yes (Y)'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'No (N)'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'No (N)'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:01:02
Un-reviewed for Safety.	System	24 Oct 2020 13:25:00
User entered 'Yes (Y)'	System	24 Oct 2020 13:25:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'No (N)'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'No (N)'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'No (N)'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'Yes (Y)'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'Lindsey'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'Baden'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'MA'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:22
User entered 'US'	System	20 Oct 2020 19:09:15

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '3'	System	09 Nov 2020 12:37:51
User entered '2'	System	26 Oct 2020 16:01:13
User entered '1'	System	20 Oct 2020 19:09:15

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:35:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
User entered '26/Oct/2020 16:01'	System	26 Oct 2020 16:01:13

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:35:54

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	09 Nov 2020 12:37:44
User entered 'I'	(b) (4), (b) (6)	26 Oct 2020 16:01:13

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered	System	20 Oct 2020 19:08:39
'USA-US078-2020-MRNA-1273-P301000007'		

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

Serious

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'Yes (Y)'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'No (N)'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'No (N)'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 16:01:02
Un-reviewed for Safety.	System	24 Oct 2020 13:25:00
User entered 'Yes (Y)'	System	24 Oct 2020 13:25:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'No (N)'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'No (N)'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'No (N)'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'Yes (Y)'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'Lindsey'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'Baden'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:03
User entered 'MA'	System	20 Oct 2020 19:08:39

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 19:09:22
User entered 'US'	System	20 Oct 2020 19:09:15

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form

Generated On: 09 Jun 2021 17:35:54

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
User entered '3'	System	09 Nov 2020 12:37:51
User entered '2'	System	26 Oct 2020 16:01:13
User entered '1'	System	20 Oct 2020 19:09:15

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:35:54

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
User entered '09/Nov/2020 07:37'	System	09 Nov 2020 12:37:51

US3432229

Folder: SAE USA-US078-2020-MRNA-1273-P301000007

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:35:54

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 02:05:28
DataPoint Verified.	(b) (4), (b) (6)	17 Nov 2020 22:19:00
User entered 'I'	(b) (4), (b) (6)	09 Nov 2020 12:37:51