

US3432517 (Prod: Brigham and Womens Hospital)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:40:03

All time stamps listed in this document are displayed in GMT

US3432517

Form: Participant Creation

Data signed: (b) (4) 19 Feb 2021 03:10:24

Generated On: 09 Jun 2021 17:40:03

Participant ID

US3432517

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

US3432517

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 03:10:38

Generated On: 09 Jun 2021 17:40:03

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

Visit date (dd MMM yyyy)	17 SEP 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3432517

Folder: Screening

Form: Demographics

Data signed: (b) (4) 19 Feb 2021 03:10:37

Generated On: 09 Jun 2021 17:40:03

Date of Birth (MMM yyyy)	(b) (6) 1964
Age	55
Age Units	YEARS
Age (Derived)	55
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	True
If race is Other, specify	LATINO
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 19 Feb 2021 03:10:37

Generated On: 09 Jun 2021 17:40:03

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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 19 Feb 2021 03:10:38

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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 03:10:38

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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 03:10:38

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Condition	GERD
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 03:10:38

Generated On: 09 Jun 2021 17:40:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 SEP 2020
Time of assessment (00:00-23:59)	09:56 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 09:56
Height (xxx.x)	175 cm
Weight (xxx.x)	059.5 kg
BMI (xxx.x)	19.42857 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 03:10:38

Generated On: 09 Jun 2021 17:40:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 19 Feb 2021 03:10:38

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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

BIOSTATISTICIAN

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 03:10:38

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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 03:10:38

Generated On: 09 Jun 2021 17:40:03

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

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 19 Feb 2021 03:10:38

Generated On: 09 Jun 2021 17:40:03

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

What was the participant's randomization number? 114261

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 03:10:38

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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 03:10:38

Generated On: 09 Jun 2021 17:40:03

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 SEP 2020
Time of assessment (00:00-23:59)	09:56 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 09:56
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)	054 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	090 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 03:10:38

Generated On: 09 Jun 2021 17:40:03

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	17 SEP 2020
Time of assessment (00:00-23:59)	11:33 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 11:33
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	050 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	160 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	090 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 03:10:38

Generated On: 09 Jun 2021 17:40:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 SEP 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 03:10:38

Generated On: 09 Jun 2021 17:40:03

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 17 SEP 2020

What was the treatment time? (00:00-23:59) 11:03 (24 HR)

Treatment Date and Time (derived) 17 SEP 2020 11:03

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 03:10:38

Generated On: 09 Jun 2021 17:40:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 SEP 2020

Collection time (00:00-23:59)

10:25 (24 HR)

Collection date and time (derived)

17 SEP 2020 10:25

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 03:10:38

Generated On: 09 Jun 2021 17:40:03

Collection date (dd MMM yyyy)			17 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:32	17 SEP 2020 10:32
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:10:38

Generated On: 09 Jun 2021 17:40:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

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

17 SEP 2020 11:53

PC Open Date & Time

17 SEP 2020 11:23

PC Close Date & Time

17 SEP 2020 13:53

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐
No ☒

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

PC Time Stamp	17 SEP 2020 22:19
PC Open Date & Time	17 SEP 2020 14:48
PC Close Date & Time	18 SEP 2020 11:59

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 23:33

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.0 °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

20 SEP 2020 01:35

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 23:04

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:03

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

96.6 °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 SEP 2020 22:49

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

22 SEP 2020 22:37

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 21:48

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 11:54

PC Open Date & Time

17 SEP 2020 11:23

PC Close Date & Time

17 SEP 2020 13:53

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

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

17 SEP 2020 22:20

PC Open Date & Time

17 SEP 2020 14:48

PC Close Date & Time

18 SEP 2020 11:59

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:03

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

18 SEP 2020 23:32

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:03

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 01:36

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 23:05

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 22:50

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 22:37

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 21:49

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

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 ☐

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 11:55
PC Open Date & Time	17 SEP 2020 11:23
PC Close Date & Time	17 SEP 2020 13:53

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

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 ☐

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 22:21
PC Open Date & Time	17 SEP 2020 14:48
PC Close Date & Time	18 SEP 2020 11:59

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:03

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 ☒

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EAB) (1725)

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:03

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 23:33
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:03

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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US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:03

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 01:37
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:03

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)

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:03

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 23:05
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:03

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 22:51
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:03

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 22:36
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:03

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)

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:03

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 21:49
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3432517

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:10:37

Generated On: 09 Jun 2021 17:40:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432517

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:10:37

Generated On: 09 Jun 2021 17:40:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432517

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:10:37

Generated On: 09 Jun 2021 17:40:03

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 1 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3432517

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:10:37

Generated On: 09 Jun 2021 17:40:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432517

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:10:37

Generated On: 09 Jun 2021 17:40:03

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3432517

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:10:37

Generated On: 09 Jun 2021 17:40:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432517

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 03:10:38

Generated On: 09 Jun 2021 17:40:03

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

Visit date (dd MMM yyyy)	15 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT2
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US3432517

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 03:10:38

Generated On: 09 Jun 2021 17:40:03

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)	15 OCT 2020
Time of assessment (00:00-23:59)	08:16 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 08:16
Temperature (xxx.x)	96.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	057 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	090 mmHg
Diastolic Blood Pressure units	MMHG

US3432517

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 03:10:38

Generated On: 09 Jun 2021 17:40:03

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	15 OCT 2020
Time of assessment (00:00-23:59)	09:33 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 09:33
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	046 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	160 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	094 mmHg
Diastolic Blood Pressure units	MMHG

US3432517

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 03:10:38

Generated On: 09 Jun 2021 17:40:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 OCT 2020

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

US3432517

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 03:10:38

Generated On: 09 Jun 2021 17:40:03

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) 15 OCT 2020

What was the treatment time? (00:00-23:59) 9:02 (24 HR)

Treatment Date and Time (derived) 15 OCT 2020 9:02

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

US3432517

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 03:10:38

Generated On: 09 Jun 2021 17:40:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 OCT 2020

Collection time (00:00-23:59)

08:30 (24 HR)

Collection date and time (derived)

15 OCT 2020 08:30

US3432517

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 19 Feb 2021 03:10:38

Generated On: 09 Jun 2021 17:40:03

Collection date (dd MMM yyyy)			15 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:40	15 OCT 2020 08:40
Nasopharyngeal Swab 2	No		

US3432517

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:10:38

Generated On: 09 Jun 2021 17:40:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

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

97.6 °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

15 OCT 2020 09:49

PC Open Date & Time

15 OCT 2020 09:22

PC Close Date & Time

15 OCT 2020 11:52

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

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 98.0 °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	15 OCT 2020 23:08
PC Open Date & Time	15 OCT 2020 12:47
PC Close Date & Time	16 OCT 2020 11:59

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 OCT 2020 22:32

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 OCT 2020 05:10

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:03

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

98.7 °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 OCT 2020 18:59

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:03

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

97.3 °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

19 OCT 2020 22:35

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:03

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

96.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 OCT 2020 20:50

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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 OCT 2020 22:35

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 OCT 2020 09:50

PC Open Date & Time

15 OCT 2020 09:22

PC Close Date & Time

15 OCT 2020 11:52

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

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

15 OCT 2020 23:10

PC Open Date & Time

15 OCT 2020 12:47

PC Close Date & Time

16 OCT 2020 11:59

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:03

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

16 OCT 2020 22:32

PC Open Date & Time

16 OCT 2020 12:00

PC Close Date & Time

17 OCT 2020 11:59

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:03

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

18 OCT 2020 05:09

PC Open Date & Time

17 OCT 2020 12:00

PC Close Date & Time

18 OCT 2020 11:59

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:03

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

18 OCT 2020 18:58

PC Open Date & Time

18 OCT 2020 12:00

PC Close Date & Time

19 OCT 2020 11:59

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:03

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

19 OCT 2020 22:35

PC Open Date & Time

19 OCT 2020 12:00

PC Close Date & Time

20 OCT 2020 11:59

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:03

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

20 OCT 2020 20:51

PC Open Date & Time

20 OCT 2020 12:00

PC Close Date & Time

21 OCT 2020 11:59

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:03

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

21 OCT 2020 22:37

PC Open Date & Time

21 OCT 2020 12:00

PC Close Date & Time

22 OCT 2020 11:59

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

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 ☐

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

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

No ☒

Yes ☐

PC Time stamp	15 OCT 2020 09:50
PC Open Date & Time	15 OCT 2020 09:22
PC Close Date & Time	15 OCT 2020 11:52

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

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 ☐

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

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

No ☒

Yes ☐

PC Time stamp	15 OCT 2020 23:11
PC Open Date & Time	15 OCT 2020 12:47
PC Close Date & Time	16 OCT 2020 11:59

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:03

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 ☒

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:03

Yes <input type="checkbox"/>	
PC Time stamp	16 OCT 2020 22:33
PC Open Date & Time	16 OCT 2020 12:00
PC Close Date & Time	17 OCT 2020 11:59

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

90 of 1966

EAB) (1725)

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:03

Yes <input type="checkbox"/>	
PC Time stamp	18 OCT 2020 05:10
PC Open Date & Time	17 OCT 2020 12:00
PC Close Date & Time	18 OCT 2020 11:59

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:03

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 ☒

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EAB) (1725)

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:03

		Yes <input type="checkbox"/>
PC Time stamp	18 OCT 2020 18:58	
PC Open Date & Time	18 OCT 2020 12:00	
PC Close Date & Time	19 OCT 2020 11:59	

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:03

Yes <input type="checkbox"/>	
PC Time stamp	19 OCT 2020 22:36
PC Open Date & Time	19 OCT 2020 12:00
PC Close Date & Time	20 OCT 2020 11:59

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:03

Yes <input type="checkbox"/>	
PC Time stamp	20 OCT 2020 20:52
PC Open Date & Time	20 OCT 2020 12:00
PC Close Date & Time	21 OCT 2020 11:59

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:03

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)

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:03

Yes <input type="checkbox"/>	
PC Time stamp	21 OCT 2020 22:37
PC Open Date & Time	21 OCT 2020 12:00
PC Close Date & Time	22 OCT 2020 11:59

US3432517

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 22 OCT 2020 23:53

PC Open Date & Time 22 OCT 2020 12:00

PC Close Date & Time 23 OCT 2020 11:59

US3432517

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 23 OCT 2020 22:29

PC Open Date & Time 23 OCT 2020 12:00

PC Close Date & Time 24 OCT 2020 11:59

US3432517

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	22 OCT 2020 23:53
PC Open Date & Time	22 OCT 2020 12:00
PC Close Date & Time	23 OCT 2020 11:59

US3432517

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	23 OCT 2020 22:29
PC Open Date & Time	23 OCT 2020 12:00
PC Close Date & Time	24 OCT 2020 11:59

US3432517

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:10:37

Generated On: 09 Jun 2021 17:40:03

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3432517

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:10:37

Generated On: 09 Jun 2021 17:40:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432517

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:10:37

Generated On: 09 Jun 2021 17:40:03

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3432517

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:10:37

Generated On: 09 Jun 2021 17:40:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432517

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:10:37

Generated On: 09 Jun 2021 17:40:03

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 5 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3432517

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:10:37

Generated On: 09 Jun 2021 17:40:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432517

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 03:10:38

Generated On: 09 Jun 2021 17:40:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3432517

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 19 Feb 2021 03:10:38

Generated On: 09 Jun 2021 17:40:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 NOV 2020
Time of assessment (00:00-23:59)	08:16 (24 HR)
Vital Signs Date and Time (derived)	12 NOV 2020 08:16
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432517

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 03:10:38

Generated On: 09 Jun 2021 17:40:03

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.

US3432517

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 03:10:38

Generated On: 09 Jun 2021 17:40:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 NOV 2020

Collection time (00:00-23:59)

08:35 (24 HR)

Collection date and time (derived)

12 NOV 2020 08:35

US3432517

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:10:38

Generated On: 09 Jun 2021 17:40:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432517

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

17 NOV 2020 09:59:17

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 NOV 2020 09:43:49
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 NOV 2020 08:22:06
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 82

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 DEC 2020 11:21:11

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 DEC 2020 08:42:27
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 DEC 2020 10:07:03
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 18:15:33

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 JAN 2021 09:50:08
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

12 JAN 2021 07:07:49

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 JAN 2021 09:27:16
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 JAN 2021 23:59:45

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 JAN 2021 09:47:11

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	08 FEB 2021 20:53:56
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 FEB 2021 12:40:21

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

22 FEB 2021 20:43:13

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

01 MAR 2021 23:39:22

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 MAR 2021 08:43:47

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 MAR 2021 08:21:51

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

24 MAR 2021 11:59:24

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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	27 MAR 2021 18:08:02
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 APR 2021 12:14:37

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 08:31:40

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 APR 2021 23:27:55

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 01:40:10

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 22:15:44

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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="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"/>

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT	DAY 243
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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 ☐

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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 ☐

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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"/>

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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 ☐

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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 ☐

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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"/>

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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 ☐

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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"/>

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 327

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

No ☐
Yes ☐

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

No ☐
Yes ☐

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

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

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

No ☐
Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐
Yes ☐

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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"/>

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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 ☐

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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"/>

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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 ☐

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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 ☐

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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 ☐

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 NOV 2021 00:01
Patient Cloud Close Date & Time	24 NOV 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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"/>

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 DEC 2021 00:01
Patient Cloud Close Date & Time	08 DEC 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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 ☐

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Open Date & Time](#)

11 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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"/>

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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 ☐

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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"/>

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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 <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"/>

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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 ☐

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 FEB 2022 00:01
Patient Cloud Close Date & Time	09 FEB 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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="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"/>

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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 ☐

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 530

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

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

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

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

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

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

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

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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 ☐

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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 ☐

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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 ☐

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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 ☐

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 593

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

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

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

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

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

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

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

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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"/>

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 635

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

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

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

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

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

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

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

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 649

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

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

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

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

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

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

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

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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 ☐

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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"/>

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 JUL 2022 00:01
Patient Cloud Close Date & Time	20 JUL 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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 ☐

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 698

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Open Date & Time](#)

13 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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 ☐

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	24 AUG 2022 23:59
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US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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"/>

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 726

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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 ☐

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 OCT 2022 00:01
Patient Cloud Close Date & Time	05 OCT 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 761

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2022 00:01
Patient Cloud Close Date & Time	19 OCT 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 OCT 2022 00:01
Patient Cloud Close Date & Time	26 OCT 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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 ☐

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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 ☐

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 NOV 2022 00:01
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Patient Cloud Close Date & Time	09 NOV 2022 23:59
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US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 NOV 2022 00:01
Patient Cloud Close Date & Time	16 NOV 2022 23:59

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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"/>

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2022 23:59

US3432517

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:40:03

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 23:51:20

US3432517

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:10:37

Generated On: 09 Jun 2021 17:40:03

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 7 DEC 2020

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

Comments

If Contact Not Made, please provide Comments

US3432517

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:10:37

Generated On: 09 Jun 2021 17:40:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432517

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:10:37

Generated On: 09 Jun 2021 17:40:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432517

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:10:37

Generated On: 09 Jun 2021 17:40:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432517

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 21:07:54

Generated On: 09 Jun 2021 17:40:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432517

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 21:07:54

Generated On: 09 Jun 2021 17:40:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432517

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 21:07:54

Generated On: 09 Jun 2021 17:40:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432517

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 21:07:54

Generated On: 09 Jun 2021 17:40:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432517

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 25 Apr 2021 11:24:43

Generated On: 09 Jun 2021 17:40:03

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

Visit date (dd MMM yyyy)	13 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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US3432517

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Apr 2021 11:24:43

Generated On: 09 Jun 2021 17:40:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 APR 2021
Time of assessment (00:00-23:59)	08:23 (24 HR)
Vital Signs Date and Time (derived)	13 APR 2021 08:23
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)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432517

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Apr 2021 11:24:43

Generated On: 09 Jun 2021 17:40:03

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.

US3432517

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Apr 2021 11:24:43

Generated On: 09 Jun 2021 17:40:03

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 APR 2021

Collection time (00:00-23:59)

08:33 (24 HR)

Collection date and time (derived)

13 APR 2021 08:33

US3432517

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 25 Apr 2021 11:24:43

Generated On: 09 Jun 2021 17:40:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432517

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

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

US3432517

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:03

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3432517

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:40:03

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"/>

US3432517

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:40:03

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3432517

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

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 03:10:37

Generated On: 09 Jun 2021 17:40:03

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

Visit date (dd MMM yyyy)	9 FEB 2021
--------------------------	------------

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

Folder OID	UNBLND_DECIDE
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US3432517

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

Form: Unblinding

Data signed: (b) (4) 04 Apr 2021 21:07:54

Generated On: 09 Jun 2021 17:40:03

Date of updated informed consent (<i>dd MMM yyyy</i>)	9 FEB 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	9 FEB 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3432517

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 19 Feb 2021 03:10:37

Generated On: 09 Jun 2021 17:40:03

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

US3432517

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 03:10:37

Generated On: 09 Jun 2021 17:40:03

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	9 FEB 2021
Time of assessment (00:00-23:59)	10:20 (24 HR)
Vital Signs Date and Time (derived)	9 FEB 2021 10:20
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	056 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	012 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	165 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	095 mmHg
Diastolic Blood Pressure units	MMHG

US3432517

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 03:10:37

Generated On: 09 Jun 2021 17:40:03

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	9 FEB 2021
Time of assessment (00:00-23:59)	11:53 (24 HR)
Vital Signs Date and Time (derived)	9 FEB 2021 11:53
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	IR
Pulse (xxx)	055 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	014 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	169 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	097 mmHg
Diastolic Blood Pressure units	MMHG

US3432517

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

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 03:10:37

Generated On: 09 Jun 2021 17:40:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 FEB 2021

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

US3432517

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

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 03:10:37

Generated On: 09 Jun 2021 17:40:03

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 9 FEB 2021

What was the treatment time? (00:00-23:59) 11:22 (24 HR)

Treatment Date and Time (derived) 9 FEB 2021 11:22

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

US3432517

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 19 Feb 2021 03:10:37

Generated On: 09 Jun 2021 17:40:03

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

Collection date (dd MMM yyyy)	9 FEB 2021
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Collection time (00:00-23:59)	10:29 (24 HR)
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Collection date and time (derived)	9 FEB 2021 10:29
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US3432517

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 19 Feb 2021 03:10:37

Generated On: 09 Jun 2021 17:40:03

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

Collection date (dd MMM yyyy)	9 FEB 2021
-------------------------------	------------

Collection time (00:00 - 23:59)	10:30
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Collection Date and Time (derived)	9 FEB 2021 10:30
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US3432517

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

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:10:37

Generated On: 09 Jun 2021 17:40:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432517

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 03:10:37

Generated On: 09 Jun 2021 17:40:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432517

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 03:10:37

Generated On: 09 Jun 2021 17:40:03

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

US3432517

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 04 Apr 2021 21:07:54

Generated On: 09 Jun 2021 17:40:03

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

Visit date (dd MMM yyyy)	8 MAR 2021
--------------------------	------------

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

Folder OID	OLD29
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US3432517

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 04 Apr 2021 21:07:54

Generated On: 09 Jun 2021 17:40:03

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)	8 MAR 2021
Time of assessment (00:00-23:59)	15:10 (24 HR)
Vital Signs Date and Time (derived)	8 MAR 2021 15:10
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	061 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	155 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	085 mmHg
Diastolic Blood Pressure units	MMHG

US3432517

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 04 Apr 2021 21:07:54

Generated On: 09 Jun 2021 17:40:03

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)	8 MAR 2021
Time of assessment (00:00-23:59)	16:06 (24 HR)
Vital Signs Date and Time (derived)	8 MAR 2021 16:06
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	048 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	159 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	089 mmHg
Diastolic Blood Pressure units	MMHG

US3432517

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 04 Apr 2021 21:07:54

Generated On: 09 Jun 2021 17:40:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 MAR 2021

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

US3432517

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 04 Apr 2021 21:07:53

Generated On: 09 Jun 2021 17:40:03

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 8 MAR 2021

What was the treatment time? (00:00-23:59) 15:32 (24 HR)

Treatment Date and Time (derived) 8 MAR 2021 15:32

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

US3432517

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 21:07:53

Generated On: 09 Jun 2021 17:40:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432517

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 04 Apr 2021 21:10:32

Generated On: 09 Jun 2021 17:40:03

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432517

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 21:10:32

Generated On: 09 Jun 2021 17:40:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432517

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 25 Apr 2021 11:24:43

Generated On: 09 Jun 2021 17:40:03

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

Visit date (dd MMM yyyy)	13 APR 2021
--------------------------	-------------

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

Folder OID	OLD57
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US3432517

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 25 Apr 2021 11:24:43

Generated On: 09 Jun 2021 17:40:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	13 APR 2021
Time of assessment (<i>00:00-23:59</i>)	08:23 (24 HR)
Vital Signs Date and Time (derived)	13 APR 2021 08:23
Temperature (<i>xxx.x</i>)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	62 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432517

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Apr 2021 11:24:43

Generated On: 09 Jun 2021 17:40:03

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.

US3432517

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Apr 2021 11:24:43

Generated On: 09 Jun 2021 17:40:03

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

Collection date (dd MMM yyyy)	13 APR 2021
-------------------------------	-------------

Collection time (00:00-23:59)	08:33 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	13 APR 2021 08:33
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US3432517

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 19 Feb 2021 03:10:24

Generated On: 09 Jun 2021 17:40:03

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3432517

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 25 Apr 2021 11:24:43

Generated On: 09 Jun 2021 17:40:03

AEID

Adverse event

LIGHTHEADEDNESS

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)

15 OCT 2020

Start time (00:00-23:59)

13:00 (24 HR)

AE start date and time (derived)

15 OCT 2020 13:00

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

15 OCT 2020

End time (00:00-23:59)

19:00 (24 HR)

AE End Date and Time (derived)

15 OCT 2020 19:00

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

PRODUCTION RELEASE (v12.003

345 of 1966

EAB) (1725)

US3432517

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 25 Apr 2021 11:24:43

Generated On: 09 Jun 2021 17:40:03

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input checked="" 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)	

US3432517

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 25 Apr 2021 11:24:43

Generated On: 09 Jun 2021 17:40:03

AEID

Adverse event

GENERALIZED MYALGIAS

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)

15 OCT 2020

Start time (00:00-23:59)

23:11 (24 HR)

AE start date and time (derived)

15 OCT 2020 23:11

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

23 OCT 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)

Data signed: (b) (4) 25 Apr 2021 11:24:43

Generated On: 09 Jun 2021 17:40:03

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input 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)	_____

US3432517

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 25 Apr 2021 11:24:43

Generated On: 09 Jun 2021 17:40:03

AEID	USA-US078-2021-MRNA-1273-P30 1000016
Adverse event	KIDNEY STONES
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)	02 FEB 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)	3 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	2 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	3 FEB 2021
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 11:24:43

Generated On: 09 Jun 2021 17:40:03

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

US3432517

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 25 Apr 2021 11:24:43

Generated On: 09 Jun 2021 17:40:03

PATIENT HOSPITALIZED
OVERNIGHT 2FEB21-3FEB21
FOR KIDNEY STONES. GIVEN
600 MG OF IBUPROFEN PRN
AND FLOMAX QD 1 PILL.
PARTICIPANT KEPT IN ED
OVERNIGHT FOR MONITORING.

CT OF ABDOMEN/PELVIS
PERFORMED 02FEB2021-
SHOWED A 4 MM STONE
WITHIN THE DISTAL LEFT
URETER

17FEB2021- FOLLOW UP. PAIN
RESOLVED BUT STONE NOT
PASSED.

01MAR2021- FOLLOW UP. PAIN
RESOLVED AND STONE
PASSED.

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

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 19 Feb 2021 03:10:37

Generated On: 09 Jun 2021 17:40:03

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

Yes ☒

No ☐

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

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 04 Apr 2021 21:07:53

Generated On: 09 Jun 2021 17:40:03

Name of Medication NAPROXEN

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED BODY
ACHES/SORENESS AFTER
RUNNING

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 04 Apr 2021 21:07:53

Generated On: 09 Jun 2021 17:40:03

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

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 04 Apr 2021 21:07:53

Generated On: 09 Jun 2021 17:40:03

Name of Medication TUMS

Prophylaxis Yes ☐
No ☒

Indication GERD

Dose per administration UNK

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 04 Apr 2021 21:07:53

Generated On: 09 Jun 2021 17:40:03

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

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 04 Apr 2021 21:07:53

Generated On: 09 Jun 2021 17:40:03

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication KIDNEY STONES

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

EVERY 6 HR PRN

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

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EAB) (1725)

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 04 Apr 2021 21:07:53

Generated On: 09 Jun 2021 17:40:03

	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)		03 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 04 Apr 2021 21:07:53

Generated On: 09 Jun 2021 17:40:03

Name of Medication FLOMAX

Prophylaxis Yes ☐
No ☒

Indication KIDNEY STONES

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 04 Apr 2021 21:07:53

Generated On: 09 Jun 2021 17:40:03

	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)		03 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 10 FEB 2021		
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"/>

US3432517

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 19 Feb 2021 03:10:37

Generated On: 09 Jun 2021 17:40:03

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3432517

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 04 Apr 2021 21:07:53

Generated On: 09 Jun 2021 17:40:03

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
03 NOV 2020	COLONOSCOPY	Diagnostic	
02 FEB 2021	CT OF ABDOMEN/PELVIS	Adverse Event	

US3432517

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:40:03

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

US3432517

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:40:03

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

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Data signed: (b) (4) 04 Apr 2021 21:07:54

Generated On: 09 Jun 2021 17:40:03

SAEID	USA-US078-2021-MRNA-1273-P301000016
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Data signed: (b) (4) 04 Apr 2021 21:07:54

Generated On: 09 Jun 2021 17:40:03

SAEID	USA-US078-2021-MRNA-1273-P301000016
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	10/FEB/2021 10:13
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

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form (2)

Data signed: (b) (4) 04 Apr 2021 21:07:54

Generated On: 09 Jun 2021 17:40:03

SAEID	USA-US078-2021-MRNA-1273-P301000016
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	02/MAR/2021 13:01
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

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form (3)

Data signed: (b) (4) 04 Apr 2021 21:07:54

Generated On: 09 Jun 2021 17:40:03

SAEID	USA-US078-2021-MRNA-1273-P301000016
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	12/MAR/2021 14:20
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

US3432517 (Prod: Brigham and Womens Hospital)

US3432517

Form: Participant Creation

Generated On: 09 Jun 2021 17:40:03

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 03:10:24
User entered 'US3432517'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	17 Sep 2020 13:54:34

US3432517

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:40:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	Megan Powell (b) (4)	17 Sep 2020 15:17:17

US3432517

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '17 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 13:54:35

US3432517

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:40:03

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Clinic (Clinic)'	Megan Powell (b) (4)	17 Sep 2020 15:17:17

US3432517

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:40:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User entered 'SCRN'	System	17 Sep 2020 15:17:17

US3432517

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:03

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered (b) (6) 1964'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 13:54:36

US3432517

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:03

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '55'	Megan Powell (b) (4)	17 Sep 2020 17:12:28

US3432517

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:03

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User entered 'YEARS'	System	17 Sep 2020 17:12:28

US3432517

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:03

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User entered '55'	System	17 Sep 2020 15:17:38

US3432517

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:03

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Male (M)'	Megan Powell (b) (4)	17 Sep 2020 17:12:28

US3432517

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:03

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Megan Powell (b) (4)	17 Sep 2020 17:12:28

US3432517

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:03

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '0'	Megan Powell (b) (4)	17 Sep 2020 17:12:28

US3432517

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:03

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '0'	Megan Powell (b) (4)	17 Sep 2020 17:12:28

US3432517

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:03

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '0'	Megan Powell (b) (4)	17 Sep 2020 17:12:28

US3432517

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:03

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '0'	Megan Powell (b) (4)	17 Sep 2020 17:12:28

US3432517

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:03

Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '0'	Megan Powell (b) (4)	17 Sep 2020 17:12:28

US3432517

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:03

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'I'	Megan Powell (b) (4)	17 Sep 2020 17:12:28

US3432517

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:03

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Latino'	Megan Powell (b) (4)	17 Sep 2020 17:12:28

US3432517

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:03

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '0'	Megan Powell (b) (4)	17 Sep 2020 17:12:28

US3432517

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:40:03

Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '0'	Megan Powell (b) (4)	17 Sep 2020 17:12:28

US3432517

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:03

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '17 Sep 2020'	Megan Powell (b) (4)	17 Sep 2020 15:17:38

US3432517

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User entered 'Sep 2020'	System	17 Sep 2020 15:17:38

US3432517

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User entered '2020'	System	17 Sep 2020 15:17:38

US3432517

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:03

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Amendment 3 (3)'	Megan Powell (b) (4)	17 Sep 2020 15:17:38

US3432517

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	Megan Powell (b) (4)	17 Sep 2020 15:17:38

US3432517

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:03

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered empty.	Megan Powell (b) (4)	17 Sep 2020 15:17:38

US3432517

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:03

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered empty.	Megan Powell (b) (4)	17 Sep 2020 15:17:38

US3432517

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:03

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'No (N)'	Megan Powell (b) (4)	17 Sep 2020 15:17:38

US3432517

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:03

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 13:54:35

US3432517

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:40:03

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User entered 'I'	System	17 Sep 2020 15:17:46

US3432517

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	Megan Powell (b) (4)	17 Sep 2020 15:17:46

US3432517

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:40:03

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	Megan Powell (b) (4)	17 Sep 2020 17:13:01

US3432517

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:18:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Sep 2020 17:18:35
Data point term sent to Coder	System	17 Sep 2020 17:17:07
User entered 'GERD'	Megan Powell (b) (4)	17 Sep 2020 17:16:07

US3432517

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'UN UNK 2015'	Megan Powell (b) (4)	17 Sep 2020 17:16:07

US3432517

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:03

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '0'	Megan Powell (b) (4)	17 Sep 2020 17:16:07

US3432517

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	Megan Powell (b) (4)	17 Sep 2020 17:16:07

US3432517

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered empty.	Megan Powell (b) (4)	17 Sep 2020 17:16:07

US3432517

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '0'	Megan Powell (b) (4)	17 Sep 2020 17:16:07

US3432517

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User entered 'Jan 2015'	System	17 Sep 2020 17:16:07

US3432517

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User entered '2015'	System	17 Sep 2020 17:16:07

US3432517

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User entered empty.	System	17 Sep 2020 17:16:07

US3432517

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User entered empty.	System	17 Sep 2020 17:16:07

US3432517

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	Megan Powell (b) (4)	17 Sep 2020 17:17:52

US3432517

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '17 Sep 2020'	Megan Powell (b) (4)	17 Sep 2020 17:17:52

US3432517

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '09:56'	Megan Powell (b) (4)	17 Sep 2020 17:17:52

US3432517

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User entered '17 Sep 2020 09:56'	System	17 Sep 2020 17:17:52

US3432517

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '175' cm	Megan Powell (b) (4)	17 Sep 2020 17:17:52
DataPoint set to visible.	(b) (4) System	17 Sep 2020 15:17:46

US3432517

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '059.5' kg	Megan Powell (b) (4)	17 Sep 2020 17:17:52
DataPoint set to visible.	(b) (4) System	17 Sep 2020 15:17:46

US3432517

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User entered '19.42857'	System	17 Sep 2020 17:17:52
DataPoint set to visible.	System	17 Sep 2020 15:17:46

US3432517

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User entered 'kg/m2'	System	17 Sep 2020 17:17:52
DataPoint set to visible.	System	17 Sep 2020 15:17:46

US3432517

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered missing code ND - Not Done.	Megan Powell (b) (4)	17 Sep 2020 17:17:52

US3432517

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered empty.	Megan Powell (b) (4)	17 Sep 2020 17:17:52

US3432517

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered empty.	Megan Powell (b) (4)	17 Sep 2020 17:17:52

US3432517

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered missing code ND - Not Done.	Megan Powell (b) (4)	17 Sep 2020 17:17:52

US3432517

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User entered 'bpm'	System	17 Sep 2020 17:17:52

US3432517

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered missing code ND - Not Done.	Megan Powell (b) (4)	17 Sep 2020 17:17:52

US3432517

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User entered 'breaths/min'	System	17 Sep 2020 17:17:52

US3432517

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered missing code ND - Not Done.	Megan Powell (b) (4)	17 Sep 2020 17:17:52

US3432517

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User entered 'mmHg'	System	17 Sep 2020 17:17:52

US3432517

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered missing code ND - Not Done.	Megan Powell (b) (4)	17 Sep 2020 17:17:52

US3432517

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User entered 'mmHg'	System	17 Sep 2020 17:17:52

US3432517

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21

US3432517

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21

US3432517

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	Megan Powell (b) (4)	17 Sep 2020 17:18:04

US3432517

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:03

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '17 Sep 2020'	Megan Powell (b) (4)	17 Sep 2020 17:18:04

US3432517

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'No (N)'	Megan Powell (b) (4)	17 Sep 2020 17:19:22

US3432517

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'No (N)'	Megan Powell (b) (4)	17 Sep 2020 17:19:22

US3432517

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'No (N)'	Megan Powell (b) (4)	17 Sep 2020 17:19:22

US3432517

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'No (N)'	Megan Powell (b) (4)	17 Sep 2020 17:19:22

US3432517

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:03

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'No (N)'	Megan Powell (b) (4)	17 Sep 2020 17:19:22

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Folder: Screening

Form: Risk of Exposure

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'No (N)'	Megan Powell (b) (4)	17 Sep 2020 17:19:22

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Folder: Screening

Form: Risk of Exposure

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Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'No (N)'	Megan Powell (b) (4)	17 Sep 2020 17:19:22

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Folder: Screening

Form: Risk of Exposure

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Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'No (N)'	Megan Powell (b) (4)	17 Sep 2020 17:19:22

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Folder: Screening

Form: Risk of Exposure

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Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'No (N)'	Megan Powell (b) (4)	17 Sep 2020 17:19:22

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Folder: Screening

Form: Risk of Exposure

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Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'No (N)'	Megan Powell (b) (4)	17 Sep 2020 17:19:22

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Folder: Screening

Form: Risk of Exposure

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Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'No (N)'	Megan Powell (b) (4)	17 Sep 2020 17:19:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:03

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	Megan Powell (b) (4)	17 Sep 2020 17:19:22

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Biostatistician'	Megan Powell (b) (4)	17 Sep 2020 17:19:22

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '0'	Megan Powell (b) (4)	17 Sep 2020 17:19:22

US3432517

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:03

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '0'	Megan Powell (b) (4)	17 Sep 2020 17:19:22

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Folder: Screening

Form: Risk of Exposure

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '0'	Megan Powell (b) (4)	17 Sep 2020 17:19:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:03

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'I'	Megan Powell (b) (4)	17 Sep 2020 17:19:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:03

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '0'	Megan Powell (b) (4)	17 Sep 2020 17:19:22

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:03

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '0'	Megan Powell (b) (4)	17 Sep 2020 17:19:22

US3432517

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:03

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '0'	Megan Powell (b) (4)	17 Sep 2020 17:19:22

US3432517

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:40:03

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 10:26:21
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered empty.	Megan Powell (b) (4)	17 Sep 2020 17:19:22

US3432517

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:40:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	Megan Powell (b) (4)	17 Sep 2020 15:18:02

US3432517

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:40:03

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '17 Sep 2020'	Megan Powell (b) (4)	17 Sep 2020 15:18:02

US3432517

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:40:03

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 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Clinic (Clinic)'	Megan Powell (b) (4)	17 Sep 2020 15:18:02

US3432517

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:40:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered 'VISIT1'	System	17 Sep 2020 15:18:02

US3432517

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '17 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 14:24:41

US3432517

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:03

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '114261'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 14:24:41

US3432517

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:03

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	17 Sep 2020 14:24:41

US3432517

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:03

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 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'No (N)'	Megan Powell (b) (4)	17 Sep 2020 17:19:52

US3432517

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:03

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 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'No (N)'	Megan Powell (b) (4)	17 Sep 2020 17:19:52

US3432517

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:03

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'No (N)'	Megan Powell (b) (4)	17 Sep 2020 17:19:52

US3432517

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:03

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'No (N)'	Megan Powell (b) (4)	17 Sep 2020 17:19:52

US3432517

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:03

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'No (N)'	Megan Powell (b) (4)	17 Sep 2020 17:19:52

US3432517

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:40:03

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'No (N)'	(b) (4), (b) (6)	06 Oct 2020 18:29:51
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 09:24:25
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 09:24:25

US3432517

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:03

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered missing code ND - Not Done.	Megan Powell (b) (4)	17 Sep 2020 17:23:02

US3432517

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:03

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered missing code ND - Not Done.	Megan Powell (b) (4)	17 Sep 2020 17:23:02

US3432517

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:03

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered missing code ND - Not Done.	Megan Powell (b) (4)	17 Sep 2020 17:23:02

US3432517

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:03

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered missing code ND - Not Done.	Megan Powell (b) (4)	17 Sep 2020 17:23:02

US3432517

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User accepted default value 'Pre-Dose (PREDOSE)'	Megan Powell (b) (4) (b) (4)	17 Sep 2020 17:23:02

US3432517

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	Megan Powell (b) (4)	17 Sep 2020 17:23:02

US3432517

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '17 Sep 2020'	Megan Powell (b) (4)	17 Sep 2020 17:23:02

US3432517

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '09:56'	Megan Powell (b) (4)	17 Sep 2020 17:23:02

US3432517

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered '17 Sep 2020 09:56'	System	17 Sep 2020 17:23:02

US3432517

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '37.0' C	Megan Powell (b) (4)	17 Sep 2020 17:23:02

US3432517

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Oral (Oral)'	Megan Powell (b) (4)	17 Sep 2020 17:23:02

US3432517

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered empty.	Megan Powell (b) (4)	17 Sep 2020 17:23:02

US3432517

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '054'	Megan Powell (b) (4)	17 Sep 2020 17:23:02

US3432517

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered 'bpm'	System	17 Sep 2020 17:23:02

US3432517

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '016'	Megan Powell (b) (4)	17 Sep 2020 17:23:02

US3432517

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered 'breaths/min'	System	17 Sep 2020 17:23:02

US3432517

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '150'	Megan Powell (b) (4)	17 Sep 2020 17:23:02

US3432517

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered 'mmHg'	System	17 Sep 2020 17:23:02

US3432517

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '090'	Megan Powell (b) (4)	17 Sep 2020 17:23:02

US3432517

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered 'mmHg'	System	17 Sep 2020 17:23:02

US3432517

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:03

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered missing code ND - Not Done.	Megan Powell (b) (4)	17 Sep 2020 17:23:02

US3432517

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:03

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered missing code ND - Not Done.	Megan Powell (b) (4)	17 Sep 2020 17:23:02

US3432517

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User accepted default value 'Post-Dose (POSTDOSE)'	Megan Powell (b) (4) (b) (4)	17 Sep 2020 17:23:02

US3432517

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	Megan Powell (b) (4)	17 Sep 2020 17:23:02

US3432517

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '17 Sep 2020'	Megan Powell (b) (4)	17 Sep 2020 17:23:02

US3432517

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '11:33'	Megan Powell (b) (4)	17 Sep 2020 17:23:02

US3432517

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered '17 Sep 2020 11:33'	System	17 Sep 2020 17:23:02

US3432517

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User closed query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 17:23:15
Query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	17 Sep 2020 17:23:15
User entered '97.7' F reason for change: Data Entry Error	Megan Powell (b) (4)	17 Sep 2020 17:23:15
User opened query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 17:23:02
User entered '97.7' C	Megan Powell (b) (4)	17 Sep 2020 17:23:02

US3432517

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Oral (Oral)'	Megan Powell (b) (4)	17 Sep 2020 17:23:02

US3432517

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered empty.	Megan Powell (b) (4)	17 Sep 2020 17:23:02

US3432517

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '050'	Megan Powell (b) (4)	17 Sep 2020 17:23:02

US3432517

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered 'bpm'	System	17 Sep 2020 17:23:02

US3432517

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '016'	Megan Powell (b) (4)	17 Sep 2020 17:23:02

US3432517

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered 'breaths/min'	System	17 Sep 2020 17:23:02

US3432517

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '160'	Megan Powell (b) (4)	17 Sep 2020 17:23:02

US3432517

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered 'mmHg'	System	17 Sep 2020 17:23:02

US3432517

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '090'	Megan Powell (b) (4)	17 Sep 2020 17:23:02

US3432517

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered 'mmHg'	System	17 Sep 2020 17:23:02

US3432517

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	Megan Powell (b) (4)	17 Sep 2020 17:23:35

US3432517

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '17 Sep 2020'	Megan Powell (b) (4)	17 Sep 2020 17:23:35

US3432517

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	Megan Powell (b) (4)	17 Sep 2020 15:19:14

US3432517

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered empty.	Megan Powell (b) (4)	17 Sep 2020 15:19:14

US3432517

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

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 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered empty.	Megan Powell (b) (4)	17 Sep 2020 15:19:14

US3432517

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered 'MRNA-1273 OR PLACEBO'	System	17 Sep 2020 15:19:14

US3432517

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '17 Sep 2020'	Megan Powell (b) (4)	17 Sep 2020 15:19:14

US3432517

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '11:03'	Megan Powell (b) (4)	17 Sep 2020 15:19:14

US3432517

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered '17 Sep 2020 11:03'	System	17 Sep 2020 15:19:14

US3432517

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Left Arm (LEFT ARM)'	Megan Powell (b) (4)	17 Sep 2020 15:19:14

US3432517

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered 'ONCE'	System	17 Sep 2020 15:19:14

US3432517

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered 'INTRAMUSCULAR'	System	17 Sep 2020 15:19:14

US3432517

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	Megan Powell (b) (4)	18 Sep 2020 00:02:07

US3432517

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '17 Sep 2020'	Megan Powell (b) (4)	18 Sep 2020 00:02:07

US3432517

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '10:25'	Megan Powell (b) (4)	18 Sep 2020 00:02:07

US3432517

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered '17 Sep 2020 10:25'	System	18 Sep 2020 00:02:07

US3432517

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:40:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '17 Sep 2020'	Megan Powell (b) (4)	18 Sep 2020 00:01:43

US3432517

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Megan Powell (b) (4) (b) (4)	18 Sep 2020 00:01:43

US3432517

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	Megan Powell (b) (4)	18 Sep 2020 00:01:43

US3432517

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '10:32'	Megan Powell (b) (4)	18 Sep 2020 00:01:43

US3432517

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:03

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered '17 Sep 2020 10:32'	System	18 Sep 2020 00:01:43

US3432517

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Megan Powell (b) (4) (b) (4)	18 Sep 2020 00:01:43

US3432517

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'No (N)'	Megan Powell (b) (4)	18 Sep 2020 00:01:43

US3432517

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered empty.	Megan Powell (b) (4)	18 Sep 2020 00:01:43

US3432517

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered empty.	System	18 Sep 2020 00:01:43

US3432517

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:40:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 18:33:34

US3432517

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:40:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered 'I'	System	24 Sep 2020 18:33:34

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	17 Sep 2020 15:19:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-17T11:53:28', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '478b528f-547c-46d2-a0e5-43956912c980' User entered 'Yes (Y)'	System	17 Sep 2020 15:53:57
	System	17 Sep 2020 15:53:57

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-17T11:53:38', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '478b528f-547c-46d2-a0e5-43956912c980' User entered '97.7'	System	17 Sep 2020 15:53:57
	System	17 Sep 2020 15:53:57

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-17T11:53:46', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '478b528f-547c-46d2-a0e5-43956912c980'	System	17 Sep 2020 15:53:57
User entered 'No (N)'	System	17 Sep 2020 15:53:57

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-17T11:53:52', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '478b528f-547c-46d2-a0e5-43956912c980' User entered '17 Sep 2020 11:53'	System	17 Sep 2020 15:53:57
	System	17 Sep 2020 15:53:57

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '17 Sep 2020 11:23'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '17 Sep 2020 13:53'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	17 Sep 2020 15:19:14
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-17T22:19:29', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '4bec045a-add5-4b77-a10b-24ba241eea93' User entered 'Yes (Y)'	System	18 Sep 2020 02:19:52
	System	18 Sep 2020 02:19:52

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-17T22:19:36', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '4bec045a-add5-4b77-a10b-24ba241eea93' User entered '97.1'	System	18 Sep 2020 02:19:52
	System	18 Sep 2020 02:19:52

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-17T22:19:40', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '4bec045a-add5-4b77-a10b-24ba241eea93'	System	18 Sep 2020 02:19:52
User entered 'No (N)'	System	18 Sep 2020 02:19:52

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-17T22:19:49', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '4bec045a-add5-4b77-a10b-24ba241eea93'	System	18 Sep 2020 02:19:52
User entered '17 Sep 2020 22:19'	System	18 Sep 2020 02:19:52

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '17 Sep 2020 14:48'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	17 Sep 2020 15:19:14
User entered 'Day 2'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-18T23:33:25', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '829a44cd-550f-47bc-8cff-becd539a3785' User entered 'Yes (Y)'	System	19 Sep 2020 03:33:45
	System	19 Sep 2020 03:33:45

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-18T23:33:31', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '829a44cd-550f-47bc-8cff-becd539a3785' User entered '97.2'	System	19 Sep 2020 03:33:45
	System	19 Sep 2020 03:33:45

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-18T23:33:35', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '829a44cd-550f-47bc-8cff-becd539a3785'	System	19 Sep 2020 03:33:45
User entered 'No (N)'	System	19 Sep 2020 03:33:45

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-18T23:33:41', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '829a44cd-550f-47bc-8cff-becd539a3785'	System	19 Sep 2020 03:33:45
User entered '18 Sep 2020 23:33'	System	19 Sep 2020 03:33:45

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	17 Sep 2020 15:19:14
User entered 'Day 3'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-20T01:35:01', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '16f964cf-b46f-4fe0-b38a-bb88bacacfd'	System	20 Sep 2020 05:35:26
User entered 'Yes (Y)'	System	20 Sep 2020 05:35:26

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-20T01:35:11', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '16f964cf-b46f-4fe0-b38a-bb88bacacfd'	System	20 Sep 2020 05:35:26
User entered '96.0'	System	20 Sep 2020 05:35:26

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-20T01:35:17', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '16f964cf-b46f-4fe0-b38a-bb88bacacfd'	System	20 Sep 2020 05:35:26
User entered 'No (N)'	System	20 Sep 2020 05:35:26

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-20T01:35:23', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '16f964cf-b46f-4fe0-b38a-bb88bacacfdd' User entered '20 Sep 2020 01:35'	System	20 Sep 2020 05:35:26
	System	20 Sep 2020 05:35:26

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	17 Sep 2020 15:19:14
User entered 'Day 4'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-20T23:04:40', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '836afa4e-3c08-4bc4-94b1-192404a979fd' User entered 'Yes (Y)'	System	21 Sep 2020 03:04:56
	System	21 Sep 2020 03:04:56

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-20T23:04:47', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '836afa4e-3c08-4bc4-94b1-192404a979fd' User entered '97.3'	System	21 Sep 2020 03:04:56
	System	21 Sep 2020 03:04:56

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-20T23:04:50', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '836afa4e-3c08-4bc4-94b1-192404a979fd' User entered 'No (N)'	System	21 Sep 2020 03:04:56
	System	21 Sep 2020 03:04:56

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-20T23:04:54', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '836afa4e-3c08-4bc4-94b1-192404a979fd' User entered '20 Sep 2020 23:04'	System	21 Sep 2020 03:04:56
	System	21 Sep 2020 03:04:56

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	17 Sep 2020 15:19:14
User entered 'Day 5'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-21T22:49:32', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'da706dff-7d34-4db3-82d3-b925584cabe1' User entered 'Yes (Y)'	System	22 Sep 2020 02:50:00
	System	22 Sep 2020 02:50:00

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-21T22:49:37', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'da706dff-7d34-4db3-82d3-b925584cabe1' User entered '96.6'	System	22 Sep 2020 02:50:00
	System	22 Sep 2020 02:50:00

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-21T22:49:50', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'da706dff-7d34-4db3-82d3-b925584cabe1'	System	22 Sep 2020 02:50:00
User entered 'No (N)'	System	22 Sep 2020 02:50:00

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-21T22:49:56', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'da706dff-7d34-4db3-82d3-b925584cabe1' User entered '21 Sep 2020 22:49'	System	22 Sep 2020 02:50:00
	System	22 Sep 2020 02:50:00

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	17 Sep 2020 15:19:14
User entered 'Day 6'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-22T22:36:49', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '097513ad-935b-47e4-81dc-c603df8ef2fd' User entered 'Yes (Y)'	System	23 Sep 2020 02:37:07
	System	23 Sep 2020 02:37:07

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-22T22:36:54', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '097513ad-935b-47e4-81dc-c603df8ef2fd' User entered '97.7'	System	23 Sep 2020 02:37:07
	System	23 Sep 2020 02:37:07

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-22T22:36:59', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '097513ad-935b-47e4-81dc-c603df8ef2fd'	System	23 Sep 2020 02:37:07
User entered 'No (N)'	System	23 Sep 2020 02:37:07

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-22T22:37:05', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '097513ad-935b-47e4-81dc-c603df8ef2fd' User entered '22 Sep 2020 22:37'	System	23 Sep 2020 02:37:07
	System	23 Sep 2020 02:37:07

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	17 Sep 2020 15:19:14
User entered 'Day 7'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-23T21:48:31', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '656f27d6-21b1-4ccc-8cbe-0da34244024a' User entered 'Yes (Y)'	System	24 Sep 2020 01:48:47
	System	24 Sep 2020 01:48:47

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-23T21:48:37', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '656f27d6-21b1-4ccc-8cbe-0da34244024a' User entered '97.8'	System	24 Sep 2020 01:48:47
	System	24 Sep 2020 01:48:47

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-23T21:48:42', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '656f27d6-21b1-4ccc-8cbe-0da34244024a' User entered 'No (N)'	System	24 Sep 2020 01:48:47
	System	24 Sep 2020 01:48:47

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-23T21:48:45', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '656f27d6-21b1-4ccc-8cbe-0da34244024a' User entered '23 Sep 2020 21:48'	System	24 Sep 2020 01:48:47
	System	24 Sep 2020 01:48:47

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	17 Sep 2020 15:19:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-17T11:54:09', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'fc363feb-3547-4c84-a799-302ce0233302'	System	17 Sep 2020 15:54:50
User entered 'None (1)'	System	17 Sep 2020 15:54:50

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-17T11:54:23', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'fc363feb-3547-4c84-a799-302ce0233302'	System	17 Sep 2020 15:54:50
User entered 'No (N)'	System	17 Sep 2020 15:54:50

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-17T11:54:32', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'fc363feb-3547-4c84-a799-302ce0233302' User entered 'No (N)'	System	17 Sep 2020 15:54:50
	System	17 Sep 2020 15:54:50

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-17T11:54:41', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'fc363feb-3547-4c84-a799-302ce0233302'	System	17 Sep 2020 15:54:50
User entered 'None (1)'	System	17 Sep 2020 15:54:50

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-17T11:54:46', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'fc363feb-3547-4c84-a799-302ce0233302'	System	17 Sep 2020 15:54:50
User entered '17 Sep 2020 11:54'	System	17 Sep 2020 15:54:50

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '17 Sep 2020 11:23'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '17 Sep 2020 13:53'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	17 Sep 2020 15:19:14
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-17T22:20:23', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '34cd294b-fb86-467a-b77c-27bd6516f75c' User entered 'None (1)'	System	18 Sep 2020 02:20:54
	System	18 Sep 2020 02:20:54

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-17T22:20:27', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '34cd294b-fb86-467a-b77c-27bd6516f75c' User entered 'No (N)'	System	18 Sep 2020 02:20:54
	System	18 Sep 2020 02:20:54

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-17T22:20:32', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '34cd294b-fb86-467a-b77c-27bd6516f75c' User entered 'No (N)'	System	18 Sep 2020 02:20:54
	System	18 Sep 2020 02:20:54

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-17T22:20:46', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '34cd294b-fb86-467a-b77c-27bd6516f75c' User entered 'None (1)'	System	18 Sep 2020 02:20:54
	System	18 Sep 2020 02:20:54

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-17T22:20:52', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '34cd294b-fb86-467a-b77c-27bd6516f75c' User entered '17 Sep 2020 22:20'	System	18 Sep 2020 02:20:54
	System	18 Sep 2020 02:20:54

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '17 Sep 2020 14:48'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	17 Sep 2020 15:19:14
User entered 'Day 2'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-18T23:32:18', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '6551a05c-4595-42ff-b725-0b64fde332cb' User entered 'None (1)'	System	19 Sep 2020 03:32:39
	System	19 Sep 2020 03:32:39

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-18T23:32:22', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '6551a05c-4595-42ff-b725-0b64fde332cb' User entered 'No (N)'	System	19 Sep 2020 03:32:39
	System	19 Sep 2020 03:32:39

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-18T23:32:26', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '6551a05c-4595-42ff-b725-0b64fde332cb' User entered 'No (N)'	System	19 Sep 2020 03:32:39
	System	19 Sep 2020 03:32:39

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-18T23:32:31', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '6551a05c-4595-42ff-b725-0b64fde332cb'	System	19 Sep 2020 03:32:39
User entered 'None (1)'	System	19 Sep 2020 03:32:39

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-18T23:32:36', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '6551a05c-4595-42ff-b725-0b64fde332cb' User entered '18 Sep 2020 23:32'	System	19 Sep 2020 03:32:39
	System	19 Sep 2020 03:32:39

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	17 Sep 2020 15:19:14
User entered 'Day 3'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-20T01:35:43', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'c9828f34-d4e6-48d2-a892-72d7ffbbde5d' User entered 'None (1)'	System	20 Sep 2020 05:36:15
	System	20 Sep 2020 05:36:15

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-20T01:35:47', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'c9828f34-d4e6-48d2-a892-72d7ffbbde5d' User entered 'No (N)'	System	20 Sep 2020 05:36:15
	System	20 Sep 2020 05:36:15

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-20T01:35:50', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'c9828f34-d4e6-48d2-a892-72d7ffbbde5d' User entered 'No (N)'	System	20 Sep 2020 05:36:15
	System	20 Sep 2020 05:36:15

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-20T01:36:08', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'c9828f34-d4e6-48d2-a892-72d7ffbbde5d' User entered 'None (1)'	System	20 Sep 2020 05:36:15
	System	20 Sep 2020 05:36:15

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-20T01:36:11', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'c9828f34-d4e6-48d2-a892-72d7ffbbde5d' User entered '20 Sep 2020 01:36'	System	20 Sep 2020 05:36:15
	System	20 Sep 2020 05:36:15

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	17 Sep 2020 15:19:14
User entered 'Day 4'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-20T23:04:58', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '4e74233a-3720-4908-8be7-dcb7870706df' User entered 'None (1)'	System	21 Sep 2020 03:05:12
	System	21 Sep 2020 03:05:12

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-20T23:05:01', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '4e74233a-3720-4908-8be7-dcb7870706df' User entered 'No (N)'	System	21 Sep 2020 03:05:12
	System	21 Sep 2020 03:05:12

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-20T23:05:04', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '4e74233a-3720-4908-8be7-dcb7870706df' User entered 'No (N)'	System	21 Sep 2020 03:05:12
	System	21 Sep 2020 03:05:12

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-20T23:05:07', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '4e74233a-3720-4908-8be7-dcb7870706df' User entered 'None (1)'	System	21 Sep 2020 03:05:12
	System	21 Sep 2020 03:05:12

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-20T23:05:09', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '4e74233a-3720-4908-8be7-dcb7870706df' User entered '20 Sep 2020 23:05'	System	21 Sep 2020 03:05:12
	System	21 Sep 2020 03:05:12

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	17 Sep 2020 15:19:14
User entered 'Day 5'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-21T22:50:01', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '87b75eca-5e7f-41c8-80ff-94f0478aadba'	System	22 Sep 2020 02:50:24
User entered 'None (1)'	System	22 Sep 2020 02:50:24

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-21T22:50:06', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '87b75eca-5e7f-41c8-80ff-94f0478aadba' User entered 'No (N)'	System	22 Sep 2020 02:50:24
	System	22 Sep 2020 02:50:24

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-21T22:50:10', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '87b75eca-5e7f-41c8-80ff-94f0478aadba' User entered 'No (N)'	System	22 Sep 2020 02:50:24
	System	22 Sep 2020 02:50:24

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-21T22:50:16', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '87b75eca-5e7f-41c8-80ff-94f0478aadba'	System	22 Sep 2020 02:50:24
User entered 'None (1)'	System	22 Sep 2020 02:50:24

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-21T22:50:20', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '87b75eca-5e7f-41c8-80ff-94f0478aadba'	System	22 Sep 2020 02:50:24
User entered '21 Sep 2020 22:50'	System	22 Sep 2020 02:50:24

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	17 Sep 2020 15:19:14
User entered 'Day 6'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-22T22:37:15', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'fef125f1-8dfb-4159-bc38-08330594b1fe'	System	23 Sep 2020 02:37:32
User entered 'None (1)'	System	23 Sep 2020 02:37:32

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-22T22:37:18', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'fef125f1-8dfb-4159-bc38-08330594b1fe' User entered 'No (N)'	System	23 Sep 2020 02:37:32
	System	23 Sep 2020 02:37:32

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-22T22:37:21', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'fef125f1-8dfb-4159-bc38-08330594b1fe' User entered 'No (N)'	System	23 Sep 2020 02:37:32
	System	23 Sep 2020 02:37:32

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-22T22:37:26', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'fef125f1-8dfb-4159-bc38-08330594b1fe'	System	23 Sep 2020 02:37:32
User entered 'None (1)'	System	23 Sep 2020 02:37:32

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-22T22:37:29', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'fef125f1-8dfb-4159-bc38-08330594b1fe' User entered '22 Sep 2020 22:37'	System	23 Sep 2020 02:37:32
	System	23 Sep 2020 02:37:32

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	17 Sep 2020 15:19:14
User entered 'Day 7'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-23T21:48:55', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '01365ad2-7040-4242-9170-a94409d33915'	System	24 Sep 2020 01:49:16
User entered 'None (1)'	System	24 Sep 2020 01:49:16

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-23T21:48:58', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '01365ad2-7040-4242-9170-a94409d33915'	System	24 Sep 2020 01:49:16
User entered 'No (N)'	System	24 Sep 2020 01:49:16

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-23T21:49:05', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '01365ad2-7040-4242-9170-a94409d33915' User entered 'No (N)'	System	24 Sep 2020 01:49:16
	System	24 Sep 2020 01:49:16

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-23T21:49:11', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '01365ad2-7040-4242-9170-a94409d33915'	System	24 Sep 2020 01:49:16
User entered 'None (1)'	System	24 Sep 2020 01:49:16

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-23T21:49:14', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '01365ad2-7040-4242-9170-a94409d33915'	System	24 Sep 2020 01:49:16
User entered '23 Sep 2020 21:49'	System	24 Sep 2020 01:49:16

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	17 Sep 2020 15:19:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-17T11:54:58', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '56221415-80ad-4f56-8584-584ad4538387' User entered 'None (0)'	System	17 Sep 2020 15:55:29
	System	17 Sep 2020 15:55:29

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-17T11:55:02', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '56221415-80ad-4f56-8584-584ad4538387' User entered 'None (0)'	System	17 Sep 2020 15:55:29
	System	17 Sep 2020 15:55:29

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-17T11:55:06', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '56221415-80ad-4f56-8584-584ad4538387' User entered 'None (0)'	System	17 Sep 2020 15:55:29
	System	17 Sep 2020 15:55:29

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-17T11:55:12', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '56221415-80ad-4f56-8584-584ad4538387' User entered 'None (0)'	System	17 Sep 2020 15:55:29
	System	17 Sep 2020 15:55:29

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-17T11:55:14', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '56221415-80ad-4f56-8584-584ad4538387' User entered 'None (0)'	System	17 Sep 2020 15:55:29
	System	17 Sep 2020 15:55:29

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-17T11:55:16', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '56221415-80ad-4f56-8584-584ad4538387' User entered 'None (0)'	System	17 Sep 2020 15:55:29
	System	17 Sep 2020 15:55:29

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-17T11:55:23', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '56221415-80ad-4f56-8584-584ad4538387' User entered 'No (N)'	System	17 Sep 2020 15:55:29
	System	17 Sep 2020 15:55:29

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-17T11:55:26', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '56221415-80ad-4f56-8584-584ad4538387'	System	17 Sep 2020 15:55:29
User entered '17 Sep 2020 11:55'	System	17 Sep 2020 15:55:29

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '17 Sep 2020 11:23'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '17 Sep 2020 13:53'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	17 Sep 2020 15:19:14
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-17T22:21:05', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '499e0af4-90b7-4f7a-aaed-e34723cac1df' User entered 'None (0)'	System	18 Sep 2020 02:21:55
	System	18 Sep 2020 02:21:55

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-17T22:21:14', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '499e0af4-90b7-4f7a-aaed-e34723cac1df' User entered 'None (0)'	System	18 Sep 2020 02:21:55
	System	18 Sep 2020 02:21:55

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-17T22:21:24', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '499e0af4-90b7-4f7a-aaed-e34723cac1df' User entered 'None (0)'	System	18 Sep 2020 02:21:55
	System	18 Sep 2020 02:21:55

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-17T22:21:32', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '499e0af4-90b7-4f7a-aaed-e34723cac1df' User entered 'None (0)'	System	18 Sep 2020 02:21:55
	System	18 Sep 2020 02:21:55

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-17T22:21:35', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '499e0af4-90b7-4f7a-aaed-e34723cac1df' User entered 'None (0)'	System	18 Sep 2020 02:21:55
	System	18 Sep 2020 02:21:55

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-17T22:21:37', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '499e0af4-90b7-4f7a-aaed-e34723cac1df' User entered 'None (0)'	System	18 Sep 2020 02:21:55
	System	18 Sep 2020 02:21:55

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-17T22:21:45', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '499e0af4-90b7-4f7a-aaed-e34723cac1df' User entered 'No (N)'	System	18 Sep 2020 02:21:55
	System	18 Sep 2020 02:21:55

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-17T22:21:53', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '499e0af4-90b7-4f7a-aaed-e34723cac1df' User entered '17 Sep 2020 22:21'	System	18 Sep 2020 02:21:55
	System	18 Sep 2020 02:21:55

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '17 Sep 2020 14:48'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	17 Sep 2020 15:19:14
User entered 'Day 2'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-18T23:32:42', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'c3261e16-6ff1-41de-80cd-a463807ef745' User entered 'None (0)'	System	19 Sep 2020 03:33:10
	System	19 Sep 2020 03:33:10

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-18T23:32:46', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'c3261e16-6ff1-41de-80cd-a463807ef745' User entered 'None (0)'	System	19 Sep 2020 03:33:10
	System	19 Sep 2020 03:33:10

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-18T23:32:51', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'c3261e16-6ff1-41de-80cd-a463807ef745' User entered 'None (0)'	System	19 Sep 2020 03:33:10
	System	19 Sep 2020 03:33:10

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-18T23:32:53', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'c3261e16-6ff1-41de-80cd-a463807ef745' User entered 'None (0)'	System	19 Sep 2020 03:33:10
	System	19 Sep 2020 03:33:10

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-18T23:32:57', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'c3261e16-6ff1-41de-80cd-a463807ef745' User entered 'None (0)'	System	19 Sep 2020 03:33:10
	System	19 Sep 2020 03:33:10

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-18T23:32:59', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'c3261e16-6ff1-41de-80cd-a463807ef745' User entered 'None (0)'	System	19 Sep 2020 03:33:10
	System	19 Sep 2020 03:33:10

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-18T23:33:03', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'c3261e16-6ff1-41de-80cd-a463807ef745'	System	19 Sep 2020 03:33:10
User entered 'No (N)'	System	19 Sep 2020 03:33:10

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-18T23:33:06', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'c3261e16-6ff1-41de-80cd-a463807ef745'	System	19 Sep 2020 03:33:10
User entered '18 Sep 2020 23:33'	System	19 Sep 2020 03:33:10

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	17 Sep 2020 15:19:14
User entered 'Day 3'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-20T01:36:18', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '8f9da9c6-efc0-4029-b04f-bce7e8f95d36' User entered 'None (0)'	System	20 Sep 2020 05:37:15
	System	20 Sep 2020 05:37:15

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-20T01:36:30', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '8f9da9c6-efc0-4029-b04f-bce7e8f95d36' User entered 'None (0)'	System	20 Sep 2020 05:37:15
	System	20 Sep 2020 05:37:15

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-20T01:36:45', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '8f9da9c6-efc0-4029-b04f-bce7e8f95d36'	System	20 Sep 2020 05:37:15
User entered 'No interference with activity (1)'	System	20 Sep 2020 05:37:15

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-20T01:36:56', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '8f9da9c6-efc0-4029-b04f-bce7e8f95d36'	System	20 Sep 2020 05:37:15
User entered 'No interference with activity (1)'	System	20 Sep 2020 05:37:15

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-20T01:36:59', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '8f9da9c6-efc0-4029-b04f-bce7e8f95d36' User entered 'None (0)'	System	20 Sep 2020 05:37:15
	System	20 Sep 2020 05:37:15

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-20T01:37:02', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '8f9da9c6-efc0-4029-b04f-bce7e8f95d36' User entered 'None (0)'	System	20 Sep 2020 05:37:15
	System	20 Sep 2020 05:37:15

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-20T01:37:07', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '8f9da9c6-efc0-4029-b04f-bce7e8f95d36'	System	20 Sep 2020 05:37:15
User entered 'No (N)'	System	20 Sep 2020 05:37:15

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-20T01:37:10', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '8f9da9c6-efc0-4029-b04f-bce7e8f95d36'	System	20 Sep 2020 05:37:15
User entered '20 Sep 2020 01:37'	System	20 Sep 2020 05:37:15

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	17 Sep 2020 15:19:14
User entered 'Day 4'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-20T23:05:14', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'bc6ef1c5-9e46-4e6f-9620-9e36a5266883' User entered 'None (0)'	System	21 Sep 2020 03:05:33
	System	21 Sep 2020 03:05:33

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-20T23:05:16', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'bc6ef1c5-9e46-4e6f-9620-9e36a5266883' User entered 'None (0)'	System	21 Sep 2020 03:05:33
	System	21 Sep 2020 03:05:33

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-20T23:05:18', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'bc6ef1c5-9e46-4e6f-9620-9e36a5266883' User entered 'None (0)'	System	21 Sep 2020 03:05:33
	System	21 Sep 2020 03:05:33

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-20T23:05:20', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'bc6ef1c5-9e46-4e6f-9620-9e36a5266883' User entered 'None (0)'	System	21 Sep 2020 03:05:33
	System	21 Sep 2020 03:05:33

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-20T23:05:22', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'bc6ef1c5-9e46-4e6f-9620-9e36a5266883' User entered 'None (0)'	System	21 Sep 2020 03:05:33
	System	21 Sep 2020 03:05:33

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-20T23:05:24', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'bc6ef1c5-9e46-4e6f-9620-9e36a5266883' User entered 'None (0)'	System	21 Sep 2020 03:05:33
	System	21 Sep 2020 03:05:33

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-20T23:05:27', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'bc6ef1c5-9e46-4e6f-9620-9e36a5266883' User entered 'No (N)'	System	21 Sep 2020 03:05:33
	System	21 Sep 2020 03:05:33

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-20T23:05:30', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'bc6ef1c5-9e46-4e6f-9620-9e36a5266883' User entered '20 Sep 2020 23:05'	System	21 Sep 2020 03:05:33
	System	21 Sep 2020 03:05:33

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	17 Sep 2020 15:19:14
User entered 'Day 5'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-21T22:50:27', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '495665ec-a3e6-4e43-89b9-8aaff0d6f5ed' User entered 'None (0)'	System	22 Sep 2020 02:51:25
	System	22 Sep 2020 02:51:25

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-21T22:50:30', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '495665ec-a3e6-4e43-89b9-8aaff0d6f5ed' User entered 'None (0)'	System	22 Sep 2020 02:51:25
	System	22 Sep 2020 02:51:25

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-21T22:50:50', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '495665ec-a3e6-4e43-89b9-8aaff0d6f5ed'	System	22 Sep 2020 02:51:25
User entered 'No interference with activity (1)'	System	22 Sep 2020 02:51:25

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-21T22:50:59', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '495665ec-a3e6-4e43-89b9-8aaff0d6f5ed' User entered 'None (0)'	System	22 Sep 2020 02:51:25
	System	22 Sep 2020 02:51:25

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-21T22:51:03', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '495665ec-a3e6-4e43-89b9-8aaff0d6f5ed' User entered 'None (0)'	System	22 Sep 2020 02:51:25
	System	22 Sep 2020 02:51:25

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-21T22:51:02', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '495665ec-a3e6-4e43-89b9-8aaff0d6f5ed' User entered 'None (0)'	System	22 Sep 2020 02:51:25
	System	22 Sep 2020 02:51:25

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-21T22:51:12', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '495665ec-a3e6-4e43-89b9-8aaff0d6f5ed' User entered 'No (N)'	System	22 Sep 2020 02:51:25
	System	22 Sep 2020 02:51:25

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-21T22:51:23', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '495665ec-a3e6-4e43-89b9-8aaff0d6f5ed' User entered '21 Sep 2020 22:51'	System	22 Sep 2020 02:51:25
	System	22 Sep 2020 02:51:25

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	17 Sep 2020 15:19:14
User entered 'Day 6'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-22T22:36:09', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '8966533e-1b6e-4131-9dba-209bbbe9038a' User entered 'None (0)'	System	23 Sep 2020 02:36:44
	System	23 Sep 2020 02:36:44

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-22T22:36:16', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '8966533e-1b6e-4131-9dba-209bbbe9038a' User entered 'None (0)'	System	23 Sep 2020 02:36:44
	System	23 Sep 2020 02:36:44

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-22T22:36:20', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '8966533e-1b6e-4131-9dba-209bbbe9038a' User entered 'None (0)'	System	23 Sep 2020 02:36:44
	System	23 Sep 2020 02:36:44

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-22T22:36:24', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '8966533e-1b6e-4131-9dba-209bbbe9038a' User entered 'None (0)'	System	23 Sep 2020 02:36:44
	System	23 Sep 2020 02:36:44

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-22T22:36:26', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '8966533e-1b6e-4131-9dba-209bbbe9038a' User entered 'None (0)'	System	23 Sep 2020 02:36:44
	System	23 Sep 2020 02:36:44

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-22T22:36:27', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '8966533e-1b6e-4131-9dba-209bbbe9038a' User entered 'None (0)'	System	23 Sep 2020 02:36:44
	System	23 Sep 2020 02:36:44

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-22T22:36:32', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '8966533e-1b6e-4131-9dba-209bbbe9038a' User entered 'No (N)'	System	23 Sep 2020 02:36:44
	System	23 Sep 2020 02:36:44

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-22T22:36:42', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '8966533e-1b6e-4131-9dba-209bbbe9038a' User entered '22 Sep 2020 22:36'	System	23 Sep 2020 02:36:44
	System	23 Sep 2020 02:36:44

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	17 Sep 2020 15:19:14
User entered 'Day 7'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-23T21:49:18', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'a233cca5-bcf4d55-b196-521023c67a7c' User entered 'None (0)'	System	24 Sep 2020 01:50:03
	System	24 Sep 2020 01:50:03

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-23T21:49:20', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'a233cca5-bcfd-4d55-b196-521023c67a7c' User entered 'None (0)'	System	24 Sep 2020 01:50:03
	System	24 Sep 2020 01:50:03

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-23T21:49:24', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'a233cca5-bcf4d55-b196-521023c67a7c' User entered 'None (0)'	System	24 Sep 2020 01:50:03
	System	24 Sep 2020 01:50:03

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-23T21:49:29', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'a233cca5-bcf4d55-b196-521023c67a7c' User entered 'None (0)'	System	24 Sep 2020 01:50:03
	System	24 Sep 2020 01:50:03

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-23T21:49:33', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'a233cca5-bcf4-4d55-b196-521023c67a7c' User entered 'None (0)'	System	24 Sep 2020 01:50:03
	System	24 Sep 2020 01:50:03

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-23T21:49:35', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'a233cca5-bcfd-4d55-b196-521023c67a7c' User entered 'None (0)'	System	24 Sep 2020 01:50:03
	System	24 Sep 2020 01:50:03

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-23T21:49:51', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'a233cca5-bcfd-4d55-b196-521023c67a7c' User entered 'No (N)'	System	24 Sep 2020 01:50:03
	System	24 Sep 2020 01:50:03

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-09-23T21:49:58', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'a233cca5-bcfd-4d55-b196-521023c67a7c' User entered '23 Sep 2020 21:49'	System	24 Sep 2020 01:50:03
	System	24 Sep 2020 01:50:03

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 15:19:14

US3432517

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 15:19:14

US3432517

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 18:33:43

US3432517

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 18:33:43

US3432517

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	24 Sep 2020 18:33:43

US3432517

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 18:33:43

US3432517

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 16:15:16

US3432517

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered 'I'	System	01 Oct 2020 16:15:16

US3432517

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:34:13
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 16:16:01

US3432517

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:34:13
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 16:16:01

US3432517

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:34:13
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Oct 2020 16:16:01

US3432517

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:34:13
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 16:16:01

US3432517

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:34:13
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 16:16:05

US3432517

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:34:13
User entered 'I'	System	01 Oct 2020 16:16:05

US3432517

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:34:13
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 20:36:16

US3432517

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:34:13
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '8 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 20:36:16

US3432517

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:34:13
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Oct 2020 20:36:16

US3432517

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:34:13
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 20:36:16

US3432517

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:34:13
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 20:36:20

US3432517

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:34:13
User entered 'I'	System	08 Oct 2020 20:36:20

US3432517

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 13:17:20

US3432517

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:03

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '15 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 13:17:20

US3432517

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:03

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 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	15 Oct 2020 13:17:20

US3432517

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered 'VISIT2'	System	15 Oct 2020 13:17:20

US3432517

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	15 Oct 2020 14:04:17

US3432517

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 14:04:17

US3432517

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '15 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 14:04:17

US3432517

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '08:16'	(b) (4), (b) (6)	15 Oct 2020 14:04:17

US3432517

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered '15 Oct 2020 08:16'	System	15 Oct 2020 14:04:17

US3432517

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	03 Nov 2020 07:52:14
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.'	(b) (4), (b) (6)	15 Oct 2020 14:08:06
answered with 'NCS' (Site from System).		
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	15 Oct 2020 14:04:17
User entered '96.7' F	(b) (4), (b) (6)	15 Oct 2020 14:04:17

US3432517

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Oral (Oral)'	(b) (4), (b) (6)	15 Oct 2020 14:04:17

US3432517

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 14:04:17

US3432517

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '057'	(b) (4), (b) (6)	15 Oct 2020 14:04:17

US3432517

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered 'bpm'	System	15 Oct 2020 14:04:17

US3432517

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '14'	(b) (4), (b) (6)	15 Oct 2020 14:04:17

US3432517

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered 'breaths/min'	System	15 Oct 2020 14:04:17

US3432517

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '158'	(b) (4), (b) (6)	15 Oct 2020 14:04:17

US3432517

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered 'mmHg'	System	15 Oct 2020 14:04:17

US3432517

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '090'	(b) (4), (b) (6)	15 Oct 2020 14:04:17

US3432517

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered 'mmHg'	System	15 Oct 2020 14:04:17

US3432517

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	15 Oct 2020 14:04:17

US3432517

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 14:04:17

US3432517

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '15 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 14:04:17

US3432517

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '09:33'	(b) (4), (b) (6)	15 Oct 2020 14:04:17

US3432517

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered '15 Oct 2020 09:33'	System	15 Oct 2020 14:04:17

US3432517

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '97.6' F	(b) (4), (b) (6)	15 Oct 2020 14:04:17

US3432517

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Oral (Oral)'	(b) (4), (b) (6)	15 Oct 2020 14:04:17

US3432517

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 14:04:17

US3432517

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '046'	(b) (4), (b) (6)	15 Oct 2020 14:04:17

US3432517

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered 'bpm'	System	15 Oct 2020 14:04:17

US3432517

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '15'	(b) (4), (b) (6)	15 Oct 2020 14:04:17

US3432517

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered 'breaths/min'	System	15 Oct 2020 14:04:17

US3432517

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '160'	(b) (4), (b) (6)	15 Oct 2020 14:04:17

US3432517

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered 'mmHg'	System	15 Oct 2020 14:04:17

US3432517

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '094'	(b) (4), (b) (6)	15 Oct 2020 14:04:17

US3432517

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered 'mmHg'	System	15 Oct 2020 14:04:17

US3432517

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 14:11:16

US3432517

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '15 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 14:11:16

US3432517

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 13:16:41

US3432517

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 13:16:41

US3432517

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

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 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 13:16:41

US3432517

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered 'MRNA-1273 OR PLACEBO'	System	15 Oct 2020 13:16:41

US3432517

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '15 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 13:16:41

US3432517

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '9:02'	(b) (4), (b) (6)	15 Oct 2020 13:16:41

US3432517

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered '15 Oct 2020 9:02'	System	15 Oct 2020 13:16:41

US3432517

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	15 Oct 2020 13:16:41

US3432517

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered 'ONCE'	System	15 Oct 2020 13:16:41

US3432517

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered 'INTRAMUSCULAR'	System	15 Oct 2020 13:16:41

US3432517

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 14:11:46

US3432517

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:03

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '15 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 14:11:46

US3432517

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '08:30'	(b) (4), (b) (6)	15 Oct 2020 14:11:46

US3432517

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:03

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered '15 Oct 2020 08:30'	System	15 Oct 2020 14:11:46

US3432517

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:40:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '15 Oct 2020'	(b) (4), (b) (6)	15 Oct 2020 14:12:25

US3432517

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	15 Oct 2020 14:12:25

US3432517

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 14:12:25

US3432517

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '08:40'	(b) (4), (b) (6)	15 Oct 2020 14:12:25

US3432517

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered '15 Oct 2020 08:40'	System	15 Oct 2020 14:12:25

US3432517

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	15 Oct 2020 14:12:25

US3432517

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'No (N)'	(b) (4), (b) (6)	15 Oct 2020 14:12:25

US3432517

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 14:12:25

US3432517

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:40:03

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered empty.	System	15 Oct 2020 14:12:25

US3432517

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 14:12:49

US3432517

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered 'I'	System	15 Oct 2020 14:12:49

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	15 Oct 2020 13:16:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-15T09:49:10', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'bcc24ba0-53ae-4754-90f1-0ca9d39bb783' User entered 'Yes (Y)'	System	15 Oct 2020 13:49:37
	System	15 Oct 2020 13:49:37

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-15T09:49:18', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'bcc24ba0-53ae-4754-90f1-0ca9d39bb783'	System	15 Oct 2020 13:49:37
User entered '97.6'	System	15 Oct 2020 13:49:37

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-15T09:49:25', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'bcc24ba0-53ae-4754-90f1-0ca9d39bb783' User entered 'No (N)'	System	15 Oct 2020 13:49:37
	System	15 Oct 2020 13:49:37

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-15T09:49:30', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'bcc24ba0-53ae-4754-90f1-0ca9d39bb783'	System	15 Oct 2020 13:49:37
User entered '15 Oct 2020 09:49'	System	15 Oct 2020 13:49:37

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '15 Oct 2020 09:22'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '15 Oct 2020 11:52'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	15 Oct 2020 13:16:41
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-15T23:08:35', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '1aa96d52-283f-42a5-a568-5a252d180018' User entered 'Yes (Y)'	System	16 Oct 2020 03:08:54
	System	16 Oct 2020 03:08:54

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-15T23:08:41', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '1aa96d52-283f-42a5-a568-5a252d180018' User entered '98.0'	System	16 Oct 2020 03:08:54
	System	16 Oct 2020 03:08:54

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-15T23:08:47', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '1aa96d52-283f-42a5-a568-5a252d180018' User entered 'No (N)'	System	16 Oct 2020 03:08:54
	System	16 Oct 2020 03:08:54

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-15T23:08:51', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '1aa96d52-283f-42a5-a568-5a252d180018' User entered '15 Oct 2020 23:08'	System	16 Oct 2020 03:08:54
	System	16 Oct 2020 03:08:54

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '15 Oct 2020 12:47'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	15 Oct 2020 13:16:41
User entered 'Day 2'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-16T22:31:49', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '0e13d715-8c7d-418a-aaa8-f09e7f44dd52'	System	17 Oct 2020 02:32:05
User entered 'Yes (Y)'	System	17 Oct 2020 02:32:05

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-16T22:31:54', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '0e13d715-8c7d-418a-aaa8-f09e7f44dd52' User entered '97.1'	System	17 Oct 2020 02:32:05
	System	17 Oct 2020 02:32:05

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-16T22:31:58', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '0e13d715-8c7d-418a-aaa8-f09e7f44dd52'	System	17 Oct 2020 02:32:05
User entered 'No (N)'	System	17 Oct 2020 02:32:05

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-16T22:32:02', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '0e13d715-8c7d-418a-aaa8-f09e7f44dd52'	System	17 Oct 2020 02:32:05
User entered '16 Oct 2020 22:32'	System	17 Oct 2020 02:32:05

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	15 Oct 2020 13:16:41
User entered 'Day 3'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-18T05:10:40', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '3721e66c-d8b4-4810-80d5-06e593f8df7c' User entered 'Yes (Y)'	System	18 Oct 2020 09:10:59
	System	18 Oct 2020 09:10:59

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-18T05:10:45', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '3721e66c-d8b4-4810-80d5-06e593f8df7c' User entered '97.1'	System	18 Oct 2020 09:10:59
	System	18 Oct 2020 09:10:59

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-18T05:10:49', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '3721e66c-d8b4-4810-80d5-06e593f8df7c' User entered 'No (N)'	System	18 Oct 2020 09:10:59
	System	18 Oct 2020 09:10:59

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-18T05:10:54', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '3721e66c-d8b4-4810-80d5-06e593f8df7c' User entered '18 Oct 2020 05:10'	System	18 Oct 2020 09:10:59
	System	18 Oct 2020 09:10:59

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	15 Oct 2020 13:16:41
User entered 'Day 4'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-18T18:58:48', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'f8f2e022-8b25-4d1f-96cd-637c382b4ef3' User entered 'Yes (Y)'	System	18 Oct 2020 22:59:06
	System	18 Oct 2020 22:59:06

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-18T18:58:57', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'f8f2e022-8b25-4d1f-96cd-637c382b4ef3' User entered '98.7'	System	18 Oct 2020 22:59:06
	System	18 Oct 2020 22:59:06

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-18T18:59:00', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'f8f2e022-8b25-4d1f-96cd-637c382b4ef3'	System	18 Oct 2020 22:59:06
User entered 'No (N)'	System	18 Oct 2020 22:59:06

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-18T18:59:04', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'f8f2e022-8b25-4d1f-96cd-637c382b4ef3' User entered '18 Oct 2020 18:59'	System	18 Oct 2020 22:59:06
	System	18 Oct 2020 22:59:06

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	15 Oct 2020 13:16:41
User entered 'Day 5'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-19T22:35:12', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '66f42a92-db8f-4f36-8223-a2e0a5a4aec8' User entered 'Yes (Y)'	System	20 Oct 2020 02:35:28
	System	20 Oct 2020 02:35:28

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-19T22:35:18', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '66f42a92-db8f-4f36-8223-a2e0a5a4aec8' User entered '97.3'	System	20 Oct 2020 02:35:28
	System	20 Oct 2020 02:35:28

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-19T22:35:23', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '66f42a92-db8f-4f36-8223-a2e0a5a4aec8'	System	20 Oct 2020 02:35:28
User entered 'No (N)'	System	20 Oct 2020 02:35:28

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-19T22:35:26', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '66f42a92-db8f-4f36-8223-a2e0a5a4aec8' User entered '19 Oct 2020 22:35'	System	20 Oct 2020 02:35:28
	System	20 Oct 2020 02:35:28

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	15 Oct 2020 13:16:41
User entered 'Day 6'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-20T20:50:16', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '60e32192-b016-495d-bf8f-2b4fd46fdc21' User entered 'Yes (Y)'	System	21 Oct 2020 00:50:38
	System	21 Oct 2020 00:50:38

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-20T20:50:24', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '60e32192-b016-495d-bf8f-2b4fd46fdc21' User entered '96.6'	System	21 Oct 2020 00:50:38
	System	21 Oct 2020 00:50:38

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-20T20:50:27', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '60e32192-b016-495d-bf8f-2b4fd46fdc21'	System	21 Oct 2020 00:50:38
User entered 'No (N)'	System	21 Oct 2020 00:50:38

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-20T20:50:36', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '60e32192-b016-495d-bf8f-2b4fd46fdc21' User entered '20 Oct 2020 20:50'	System	21 Oct 2020 00:50:38
	System	21 Oct 2020 00:50:38

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	15 Oct 2020 13:16:41
User entered 'Day 7'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-21T22:35:18', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '79a4defe-d1ad-4e27-b746-65d7dedc6108' User entered 'Yes (Y)'	System	22 Oct 2020 02:35:50
	System	22 Oct 2020 02:35:50

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-21T22:35:25', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '79a4defe-d1ad-4e27-b746-65d7dedc6108' User entered '97.6'	System	22 Oct 2020 02:35:50
	System	22 Oct 2020 02:35:50

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-21T22:35:37', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '79a4defe-d1ad-4e27-b746-65d7dedc6108'	System	22 Oct 2020 02:35:50
User entered 'No (N)'	System	22 Oct 2020 02:35:50

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-21T22:35:44', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '79a4defe-d1ad-4e27-b746-65d7dedc6108'	System	22 Oct 2020 02:35:50
User entered '21 Oct 2020 22:35'	System	22 Oct 2020 02:35:50

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	15 Oct 2020 13:16:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-15T09:49:40', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'a40b0833-965f-45a9-a8b7-36f5f0fd5593'	System	15 Oct 2020 13:50:06
User entered 'None (1)'	System	15 Oct 2020 13:50:06

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-15T09:49:49', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'a40b0833-965f-45a9-a8b7-36f5f0fd5593'	System	15 Oct 2020 13:50:06
User entered 'No (N)'	System	15 Oct 2020 13:50:06

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-15T09:49:53', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'a40b0833-965f-45a9-a8b7-36f5f0fd5593'	System	15 Oct 2020 13:50:06
User entered 'No (N)'	System	15 Oct 2020 13:50:06

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-15T09:49:59', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'a40b0833-965f-45a9-a8b7-36f5f0fd5593'	System	15 Oct 2020 13:50:06
User entered 'None (1)'	System	15 Oct 2020 13:50:06

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-15T09:50:03', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'a40b0833-965f-45a9-a8b7-36f5f0fd5593'	System	15 Oct 2020 13:50:06
User entered '15 Oct 2020 09:50'	System	15 Oct 2020 13:50:06

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '15 Oct 2020 09:22'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '15 Oct 2020 11:52'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	15 Oct 2020 13:16:41
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-15T23:09:29', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '256e4503-d4d7-403c-9826-e3c6037005b7'	System	16 Oct 2020 03:10:34
User entered 'None (1)'	System	16 Oct 2020 03:10:34

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-15T23:09:54', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '256e4503-d4d7-403c-9826-e3c6037005b7'	System	16 Oct 2020 03:10:34
User entered 'No (N)'	System	16 Oct 2020 03:10:34

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-15T23:10:08', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '256e4503-d4d7-403c-9826-e3c6037005b7'	System	16 Oct 2020 03:10:34
User entered 'No (N)'	System	16 Oct 2020 03:10:34

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-15T23:10:23', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '256e4503-d4d7-403c-9826-e3c6037005b7'	System	16 Oct 2020 03:10:34
User entered 'None (1)'	System	16 Oct 2020 03:10:34

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-15T23:10:31', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '256e4503-d4d7-403c-9826-e3c6037005b7'	System	16 Oct 2020 03:10:34
User entered '15 Oct 2020 23:10'	System	16 Oct 2020 03:10:34

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '15 Oct 2020 12:47'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	15 Oct 2020 13:16:41
User entered 'Day 2'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-16T22:32:11', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '28576f7f-60da-4dbf-9b74-57e45d8a063c'	System	17 Oct 2020 02:33:00
User entered 'None (1)'	System	17 Oct 2020 02:33:00

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-16T22:32:16', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '28576f7f-60da-4dbf-9b74-57e45d8a063c' User entered 'No (N)'	System	17 Oct 2020 02:33:00
	System	17 Oct 2020 02:33:00

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-16T22:32:47', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '28576f7f-60da-4dbf-9b74-57e45d8a063c' User entered 'No (N)'	System	17 Oct 2020 02:33:00
	System	17 Oct 2020 02:33:00

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-16T22:32:50', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '28576f7f-60da-4dbf-9b74-57e45d8a063c' User entered 'None (1)'	System	17 Oct 2020 02:33:00
	System	17 Oct 2020 02:33:00

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-16T22:32:56', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '28576f7f-60da-4dbf-9b74-57e45d8a063c' User entered '16 Oct 2020 22:32'	System	17 Oct 2020 02:33:00
	System	17 Oct 2020 02:33:00

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	15 Oct 2020 13:16:41
User entered 'Day 3'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-18T05:09:25', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '6d01739f-b4f9-4c64-b57f-8100ed57d2f4'	System	18 Oct 2020 09:09:46
User entered 'None (1)'	System	18 Oct 2020 09:09:46

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-18T05:09:28', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '6d01739f-b4f9-4c64-b57f-8100ed57d2f4' User entered 'No (N)'	System	18 Oct 2020 09:09:46
	System	18 Oct 2020 09:09:46

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-18T05:09:31', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '6d01739f-b4f9-4c64-b57f-8100ed57d2f4'	System	18 Oct 2020 09:09:46
User entered 'No (N)'	System	18 Oct 2020 09:09:46

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-18T05:09:37', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '6d01739f-b4f9-4c64-b57f-8100ed57d2f4'	System	18 Oct 2020 09:09:46
User entered 'None (1)'	System	18 Oct 2020 09:09:46

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-18T05:09:40', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '6d01739f-b4f9-4c64-b57f-8100ed57d2f4' User entered '18 Oct 2020 05:09'	System	18 Oct 2020 09:09:46
	System	18 Oct 2020 09:09:46

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	15 Oct 2020 13:16:41
User entered 'Day 4'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-18T18:58:05', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '3656f388-df0d-4ab0-9ef6-17aff60206b7'	System	18 Oct 2020 22:58:21
User entered 'None (1)'	System	18 Oct 2020 22:58:21

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-18T18:58:08', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '3656f388-df0d-4ab0-9ef6-17aff60206b7' User entered 'No (N)'	System	18 Oct 2020 22:58:21
	System	18 Oct 2020 22:58:21

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-18T18:58:10', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '3656f388-df0d-4ab0-9ef6-17aff60206b7' User entered 'No (N)'	System	18 Oct 2020 22:58:21
	System	18 Oct 2020 22:58:21

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-18T18:58:14', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '3656f388-df0d-4ab0-9ef6-17aff60206b7'	System	18 Oct 2020 22:58:21
User entered 'None (1)'	System	18 Oct 2020 22:58:21

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-18T18:58:17', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '3656f388-df0d-4ab0-9ef6-17aff60206b7' User entered '18 Oct 2020 18:58'	System	18 Oct 2020 22:58:21
	System	18 Oct 2020 22:58:21

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	15 Oct 2020 13:16:41
User entered 'Day 5'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-19T22:35:32', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'db3094e4-9da7-4214-bd5e-12f1840a74bd' User entered 'None (1)'	System	20 Oct 2020 02:35:44
	System	20 Oct 2020 02:35:44

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-19T22:35:35', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'db3094e4-9da7-4214-bd5e-12f1840a74bd' User entered 'No (N)'	System	20 Oct 2020 02:35:44
	System	20 Oct 2020 02:35:44

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-19T22:35:37', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'db3094e4-9da7-4214-bd5e-12f1840a74bd' User entered 'No (N)'	System	20 Oct 2020 02:35:44
	System	20 Oct 2020 02:35:44

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-19T22:35:40', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'db3094e4-9da7-4214-bd5e-12f1840a74bd' User entered 'None (1)'	System	20 Oct 2020 02:35:44
	System	20 Oct 2020 02:35:44

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-19T22:35:42', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'db3094e4-9da7-4214-bd5e-12f1840a74bd' User entered '19 Oct 2020 22:35'	System	20 Oct 2020 02:35:44
	System	20 Oct 2020 02:35:44

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	15 Oct 2020 13:16:41
User entered 'Day 6'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-20T20:50:57', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'be4164cc-90a2-4c2b-9e77-c32d7dbbf92a' User entered 'None (1)'	System	21 Oct 2020 00:51:28
	System	21 Oct 2020 00:51:28

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-20T20:51:10', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'be4164cc-90a2-4c2b-9e77-c32d7dbbf92a' User entered 'No (N)'	System	21 Oct 2020 00:51:28
	System	21 Oct 2020 00:51:28

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-20T20:51:18', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'be4164cc-90a2-4c2b-9e77-c32d7dbbf92a' User entered 'No (N)'	System	21 Oct 2020 00:51:28
	System	21 Oct 2020 00:51:28

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-20T20:51:23', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'be4164cc-90a2-4c2b-9e77-c32d7dbbf92a' User entered 'None (1)'	System	21 Oct 2020 00:51:28
	System	21 Oct 2020 00:51:28

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-20T20:51:26', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'be4164cc-90a2-4c2b-9e77-c32d7dbbf92a' User entered '20 Oct 2020 20:51'	System	21 Oct 2020 00:51:28
	System	21 Oct 2020 00:51:28

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	15 Oct 2020 13:16:41
User entered 'Day 7'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-21T22:37:07', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'bc79bf9c-a00e-4044-8e0b-ec4612789805'	System	22 Oct 2020 02:37:30
User entered 'None (1)'	System	22 Oct 2020 02:37:30

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-21T22:37:10', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'bc79bf9c-a00e-4044-8e0b-ec4612789805' User entered 'No (N)'	System	22 Oct 2020 02:37:30
	System	22 Oct 2020 02:37:30

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-21T22:37:13', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'bc79bf9c-a00e-4044-8e0b-ec4612789805'	System	22 Oct 2020 02:37:30
User entered 'No (N)'	System	22 Oct 2020 02:37:30

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:03

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-21T22:37:19', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'bc79bf9c-a00e-4044-8e0b-ec4612789805'	System	22 Oct 2020 02:37:30
User entered 'None (1)'	System	22 Oct 2020 02:37:30

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-21T22:37:26', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'bc79bf9c-a00e-4044-8e0b-ec4612789805'	System	22 Oct 2020 02:37:30
User entered '21 Oct 2020 22:37'	System	22 Oct 2020 02:37:30

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	15 Oct 2020 13:16:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-15T09:50:10', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '02f2c1ac-48b3-492c-a2f4-c62266af260b' User entered 'None (0)'	System	15 Oct 2020 13:50:43
	System	15 Oct 2020 13:50:43

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-15T09:50:13', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '02f2c1ac-48b3-492c-a2f4-c62266af260b' User entered 'None (0)'	System	15 Oct 2020 13:50:43
	System	15 Oct 2020 13:50:43

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-15T09:50:17', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '02f2c1ac-48b3-492c-a2f4-c62266af260b' User entered 'None (0)'	System	15 Oct 2020 13:50:43
	System	15 Oct 2020 13:50:43

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-15T09:50:20', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '02f2c1ac-48b3-492c-a2f4-c62266af260b' User entered 'None (0)'	System	15 Oct 2020 13:50:43
	System	15 Oct 2020 13:50:43

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-15T09:50:26', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '02f2c1ac-48b3-492c-a2f4-c62266af260b' User entered 'None (0)'	System	15 Oct 2020 13:50:43
	System	15 Oct 2020 13:50:43

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-15T09:50:28', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '02f2c1ac-48b3-492c-a2f4-c62266af260b' User entered 'None (0)'	System	15 Oct 2020 13:50:43
	System	15 Oct 2020 13:50:43

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-15T09:50:37', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '02f2c1ac-48b3-492c-a2f4-c62266af260b' User entered 'No (N)'	System	15 Oct 2020 13:50:43
	System	15 Oct 2020 13:50:43

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-15T09:50:40', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '02f2c1ac-48b3-492c-a2f4-c62266af260b' User entered '15 Oct 2020 09:50'	System	15 Oct 2020 13:50:43
	System	15 Oct 2020 13:50:43

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '15 Oct 2020 09:22'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '15 Oct 2020 11:52'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	15 Oct 2020 13:16:41
User entered 'Day 1, after vaccination (at home)'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-15T23:10:40', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '8abeaaa9-825d-450c-9b45-b02893dd0135'	System	16 Oct 2020 03:11:31
User entered 'No interference with activity (1)'	System	16 Oct 2020 03:11:31

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-15T23:10:50', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '8abeaaa9-825d-450c-9b45-b02893dd0135'	System	16 Oct 2020 03:11:31
User entered 'No interference with activity (1)'	System	16 Oct 2020 03:11:31

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-15T23:10:57', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '8abeaaa9-825d-450c-9b45-b02893dd0135'	System	16 Oct 2020 03:11:31
User entered 'No interference with activity (1)'	System	16 Oct 2020 03:11:31

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-15T23:11:07', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '8abeaaa9-825d-450c-9b45-b02893dd0135'	System	16 Oct 2020 03:11:31
User entered 'No interference with activity (1)'	System	16 Oct 2020 03:11:31

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-15T23:11:10', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '8abeaaa9-825d-450c-9b45-b02893dd0135' User entered 'None (0)'	System	16 Oct 2020 03:11:31
	System	16 Oct 2020 03:11:31

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-15T23:11:14', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '8abeaaa9-825d-450c-9b45-b02893dd0135' User entered 'None (0)'	System	16 Oct 2020 03:11:31
	System	16 Oct 2020 03:11:31

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-15T23:11:25', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '8abeaaa9-825d-450c-9b45-b02893dd0135'	System	16 Oct 2020 03:11:31
User entered 'No (N)'	System	16 Oct 2020 03:11:31

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-15T23:11:28', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '8abeaaa9-825d-450c-9b45-b02893dd0135' User entered '15 Oct 2020 23:11'	System	16 Oct 2020 03:11:31
	System	16 Oct 2020 03:11:31

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '15 Oct 2020 12:47'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '16 Oct 2020 11:59'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	15 Oct 2020 13:16:41
User entered 'Day 2'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-16T22:33:01', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '01e91efd-2409-48c5-b298-6dfb001849ef'	System	17 Oct 2020 02:33:30
User entered 'No interference with activity (1)'	System	17 Oct 2020 02:33:30

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-16T22:33:08', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '01e91efd-2409-48c5-b298-6dfb001849ef'	System	17 Oct 2020 02:33:30
User entered 'No interference with activity (1)'	System	17 Oct 2020 02:33:30

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-16T22:33:13', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '01e91efd-2409-48c5-b298-6dfb001849ef'	System	17 Oct 2020 02:33:30
User entered 'No interference with activity (1)'	System	17 Oct 2020 02:33:30

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-16T22:33:15', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '01e91efd-2409-48c5-b298-6dfb001849ef'	System	17 Oct 2020 02:33:30
User entered 'No interference with activity (1)'	System	17 Oct 2020 02:33:30

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-16T22:33:18', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '01e91efd-2409-48c5-b298-6dfb001849ef' User entered 'None (0)'	System	17 Oct 2020 02:33:30
	System	17 Oct 2020 02:33:30

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-16T22:33:20', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '01e91efd-2409-48c5-b298-6dfb001849ef' User entered 'None (0)'	System	17 Oct 2020 02:33:30
	System	17 Oct 2020 02:33:30

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-16T22:33:23', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '01e91efd-2409-48c5-b298-6dfb001849ef' User entered 'No (N)'	System	17 Oct 2020 02:33:30
	System	17 Oct 2020 02:33:30

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-16T22:33:26', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '01e91efd-2409-48c5-b298-6dfb001849ef' User entered '16 Oct 2020 22:33'	System	17 Oct 2020 02:33:30
	System	17 Oct 2020 02:33:30

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '16 Oct 2020 12:00'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '17 Oct 2020 11:59'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	15 Oct 2020 13:16:41
User entered 'Day 3'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-18T05:10:01', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'dc5055ad-e3c8-4724-b8de-602fb9fc97ac'	System	18 Oct 2020 09:10:35
User entered 'None (0)'	System	18 Oct 2020 09:10:35

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-18T05:10:05', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'dc5055ad-e3c8-4724-b8de-602fb9fc97ac'	System	18 Oct 2020 09:10:35
User entered 'None (0)'	System	18 Oct 2020 09:10:35

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-18T05:10:14', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'dc5055ad-e3c8-4724-b8de-602fb9fc97ac'	System	18 Oct 2020 09:10:35
User entered 'No interference with activity (1)'	System	18 Oct 2020 09:10:35

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-18T05:10:20', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'dc5055ad-e3c8-4724-b8de-602fb9fc97ac'	System	18 Oct 2020 09:10:35
User entered 'No interference with activity (1)'	System	18 Oct 2020 09:10:35

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-18T05:10:23', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'dc5055ad-e3c8-4724-b8de-602fb9fc97ac' User entered 'None (0)'	System	18 Oct 2020 09:10:35
	System	18 Oct 2020 09:10:35

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-18T05:10:25', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'dc5055ad-e3c8-4724-b8de-602fb9fc97ac' User entered 'None (0)'	System	18 Oct 2020 09:10:35
	System	18 Oct 2020 09:10:35

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-18T05:10:29', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'dc5055ad-e3c8-4724-b8de-602fb9fc97ac'	System	18 Oct 2020 09:10:35
User entered 'No (N)'	System	18 Oct 2020 09:10:35

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-18T05:10:31', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'dc5055ad-e3c8-4724-b8de-602fb9fc97ac'	System	18 Oct 2020 09:10:35
User entered '18 Oct 2020 05:10'	System	18 Oct 2020 09:10:35

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '17 Oct 2020 12:00'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '18 Oct 2020 11:59'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	15 Oct 2020 13:16:41
User entered 'Day 4'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-18T18:58:21', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'ab58570f-d8dc-4680-bddb-c8923a84dfca' User entered 'None (0)'	System	18 Oct 2020 22:58:39
	System	18 Oct 2020 22:58:39

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-18T18:58:23', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'ab58570f-d8dc-4680-bddb-c8923a84dfca' User entered 'None (0)'	System	18 Oct 2020 22:58:39
	System	18 Oct 2020 22:58:39

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-18T18:58:26', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'ab58570f-d8dc-4680-bddb-c8923a84dfca' User entered 'None (0)'	System	18 Oct 2020 22:58:39
	System	18 Oct 2020 22:58:39

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-18T18:58:28', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'ab58570f-d8dc-4680-bddb-c8923a84dfca' User entered 'None (0)'	System	18 Oct 2020 22:58:39
	System	18 Oct 2020 22:58:39

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-18T18:58:30', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'ab58570f-d8dc-4680-bddb-c8923a84dfca' User entered 'None (0)'	System	18 Oct 2020 22:58:39
	System	18 Oct 2020 22:58:39

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-18T18:58:32', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'ab58570f-d8dc-4680-bddb-c8923a84dfca' User entered 'None (0)'	System	18 Oct 2020 22:58:39
	System	18 Oct 2020 22:58:39

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-18T18:58:34', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'ab58570f-d8dc-4680-bddb-c8923a84dfca' User entered 'No (N)'	System	18 Oct 2020 22:58:39
	System	18 Oct 2020 22:58:39

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-18T18:58:37', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'ab58570f-d8dc-4680-bddb-c8923a84dfca' User entered '18 Oct 2020 18:58'	System	18 Oct 2020 22:58:39
	System	18 Oct 2020 22:58:39

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '18 Oct 2020 12:00'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '19 Oct 2020 11:59'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	15 Oct 2020 13:16:41
User entered 'Day 5'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-19T22:35:46', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '7a5327ca-247e-4228-9422-efc0e8d92113' User entered 'None (0)'	System	20 Oct 2020 02:36:10
	System	20 Oct 2020 02:36:10

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-19T22:35:48', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '7a5327ca-247e-4228-9422-efc0e8d92113' User entered 'None (0)'	System	20 Oct 2020 02:36:10
	System	20 Oct 2020 02:36:10

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-19T22:35:50', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '7a5327ca-247e-4228-9422-efc0e8d92113' User entered 'None (0)'	System	20 Oct 2020 02:36:10
	System	20 Oct 2020 02:36:10

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-19T22:35:52', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '7a5327ca-247e-4228-9422-efc0e8d92113' User entered 'None (0)'	System	20 Oct 2020 02:36:10
	System	20 Oct 2020 02:36:10

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-19T22:35:54', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '7a5327ca-247e-4228-9422-efc0e8d92113' User entered 'None (0)'	System	20 Oct 2020 02:36:10
	System	20 Oct 2020 02:36:10

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-19T22:35:56', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '7a5327ca-247e-4228-9422-efc0e8d92113' User entered 'None (0)'	System	20 Oct 2020 02:36:10
	System	20 Oct 2020 02:36:10

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-19T22:36:03', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '7a5327ca-247e-4228-9422-efc0e8d92113' User entered 'No (N)'	System	20 Oct 2020 02:36:10
	System	20 Oct 2020 02:36:10

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-19T22:36:06', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '7a5327ca-247e-4228-9422-efc0e8d92113' User entered '19 Oct 2020 22:36'	System	20 Oct 2020 02:36:10
	System	20 Oct 2020 02:36:10

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '19 Oct 2020 12:00'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '20 Oct 2020 11:59'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	15 Oct 2020 13:16:41
User entered 'Day 6'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-20T20:52:02', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '06c9ce73-24d7-4f01-aef8-71055352d433'	System	21 Oct 2020 00:52:39
User entered 'No interference with activity (1)'	System	21 Oct 2020 00:52:39

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-20T20:52:06', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '06c9ce73-24d7-4f01-aef8-71055352d433'	System	21 Oct 2020 00:52:39
User entered 'No interference with activity (1)'	System	21 Oct 2020 00:52:39

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-20T20:52:09', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '06c9ce73-24d7-4f01-aef8-71055352d433'	System	21 Oct 2020 00:52:39
User entered 'No interference with activity (1)'	System	21 Oct 2020 00:52:39

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-20T20:52:19', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '06c9ce73-24d7-4f01-aef8-71055352d433'	System	21 Oct 2020 00:52:39
User entered 'No interference with activity (1)'	System	21 Oct 2020 00:52:39

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-20T20:52:21', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '06c9ce73-24d7-4f01-aef8-71055352d433' User entered 'None (0)'	System	21 Oct 2020 00:52:39
	System	21 Oct 2020 00:52:39

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-20T20:52:23', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '06c9ce73-24d7-4f01-aef8-71055352d433' User entered 'None (0)'	System	21 Oct 2020 00:52:39
	System	21 Oct 2020 00:52:39

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-20T20:52:29', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '06c9ce73-24d7-4f01-aef8-71055352d433' User entered 'No (N)'	System	21 Oct 2020 00:52:39
	System	21 Oct 2020 00:52:39

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-20T20:52:31', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '06c9ce73-24d7-4f01-aef8-71055352d433' User entered '20 Oct 2020 20:52'	System	21 Oct 2020 00:52:39
	System	21 Oct 2020 00:52:39

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '20 Oct 2020 12:00'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '21 Oct 2020 11:59'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	15 Oct 2020 13:16:41
User entered 'Day 7'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-21T22:37:30', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '5bb589a7-c01f-4761-ad3f-309996b00705' User entered 'None (0)'	System	22 Oct 2020 02:37:56
	System	22 Oct 2020 02:37:56

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-21T22:37:34', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '5bb589a7-c01f-4761-ad3f-309996b00705' User entered 'None (0)'	System	22 Oct 2020 02:37:56
	System	22 Oct 2020 02:37:56

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-21T22:37:38', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '5bb589a7-c01f-4761-ad3f-309996b00705'	System	22 Oct 2020 02:37:56
User entered 'No interference with activity (1)'	System	22 Oct 2020 02:37:56

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-21T22:37:40', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '5bb589a7-c01f-4761-ad3f-309996b00705' User entered 'None (0)'	System	22 Oct 2020 02:37:56
	System	22 Oct 2020 02:37:56

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-21T22:37:42', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '5bb589a7-c01f-4761-ad3f-309996b00705' User entered 'None (0)'	System	22 Oct 2020 02:37:56
	System	22 Oct 2020 02:37:56

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-21T22:37:44', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '5bb589a7-c01f-4761-ad3f-309996b00705' User entered 'None (0)'	System	22 Oct 2020 02:37:56
	System	22 Oct 2020 02:37:56

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-21T22:37:48', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '5bb589a7-c01f-4761-ad3f-309996b00705' User entered 'No (N)'	System	22 Oct 2020 02:37:56
	System	22 Oct 2020 02:37:56

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-21T22:37:53', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '5bb589a7-c01f-4761-ad3f-309996b00705' User entered '21 Oct 2020 22:37'	System	22 Oct 2020 02:37:56
	System	22 Oct 2020 02:37:56

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '21 Oct 2020 12:00'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '22 Oct 2020 11:59'	System	15 Oct 2020 13:16:41

US3432517

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	21 Oct 2020 00:52:39
User entered 'Day 8'	System	21 Oct 2020 00:52:39

US3432517

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:40:03

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-22T23:53:05', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '3e50ec32-02c1-4d64-abd9-6326d270f401'	System	23 Oct 2020 03:53:14
User entered 'No interference with activity (1)'	System	23 Oct 2020 03:53:14

US3432517

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:40:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-22T23:53:09', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '3e50ec32-02c1-4d64-abd9-6326d270f401' User entered '22 Oct 2020 23:53'	System	23 Oct 2020 03:53:14
	System	23 Oct 2020 03:53:14

US3432517

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 00:52:39

US3432517

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 00:52:39

US3432517

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	22 Oct 2020 02:37:56
User entered 'Day 9'	System	22 Oct 2020 02:37:56

US3432517

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:40:03

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-23T22:29:01', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '9677b8f2-32b9-443f-bdaa-366e8a092d53'	System	24 Oct 2020 02:29:10
User entered 'None (0)'	System	24 Oct 2020 02:29:10

US3432517

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:40:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-23T22:29:04', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '9677b8f2-32b9-443f-bdaa-366e8a092d53'	System	24 Oct 2020 02:29:10
User entered '23 Oct 2020 22:29'	System	24 Oct 2020 02:29:10

US3432517

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 02:37:56

US3432517

Folder: Diary Dose 2 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 02:37:56

US3432517

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	21 Oct 2020 00:52:39
User entered 'Day 8'	System	21 Oct 2020 00:52:39

US3432517

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-22T23:53:14', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'e9714ac5-9c72-4156-902d-44a0cad3a16a' User entered 'No (N)'	System	23 Oct 2020 03:53:21
	System	23 Oct 2020 03:53:21

US3432517

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:40:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-22T23:53:17', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'e9714ac5-9c72-4156-902d-44a0cad3a16a' User entered '22 Oct 2020 23:53'	System	23 Oct 2020 03:53:21
	System	23 Oct 2020 03:53:21

US3432517

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '22 Oct 2020 12:00'	System	21 Oct 2020 00:52:39

US3432517

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '23 Oct 2020 11:59'	System	21 Oct 2020 00:52:39

US3432517

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	22 Oct 2020 02:37:56
User entered 'Day 9'	System	22 Oct 2020 02:37:56

US3432517

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-23T22:29:11', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'f8af079b-75ad-4be4-908b-275c24111378' User entered 'No (N)'	System	24 Oct 2020 02:29:16
	System	24 Oct 2020 02:29:16

US3432517

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:40:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-10-23T22:29:14', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'f8af079b-75ad-4be4-908b-275c24111378' User entered '23 Oct 2020 22:29'	System	24 Oct 2020 02:29:16
	System	24 Oct 2020 02:29:16

US3432517

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:40:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '23 Oct 2020 12:00'	System	22 Oct 2020 02:37:56

US3432517

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:40:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
User entered '24 Oct 2020 11:59'	System	22 Oct 2020 02:37:56

US3432517

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:34:13
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	23 Oct 2020 19:02:41

US3432517

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:34:13
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '23 Oct 2020'	Phoebe Cunningham (b) (4)	23 Oct 2020 19:02:41

US3432517

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:34:13
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	23 Oct 2020 19:02:41

US3432517

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:34:13
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered empty.	Phoebe Cunningham (b) (4)	23 Oct 2020 19:02:41

US3432517

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:34:13
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	23 Oct 2020 19:02:44

US3432517

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:34:13
User entered 'I'	System	23 Oct 2020 19:02:44

US3432517

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 16:19:40

US3432517

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '29 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 16:19:40

US3432517

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	29 Oct 2020 16:19:40

US3432517

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 16:19:40

US3432517

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 16:20:16

US3432517

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered 'I'	System	29 Oct 2020 16:20:16

US3432517

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	05 Nov 2020 18:18:23

US3432517

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '5 Nov 2020'	Kathleen Garvey (b) (4)	05 Nov 2020 18:18:23

US3432517

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Contact Made (CONTACT MADE)'	Kathleen Garvey (b) (4)	05 Nov 2020 18:18:23

US3432517

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered empty.	Kathleen Garvey (b) (4)	05 Nov 2020 18:18:23

US3432517

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	05 Nov 2020 18:19:25

US3432517

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered 'I'	System	05 Nov 2020 18:19:25

US3432517

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 14:48:34

US3432517

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:03

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 14:48:34

US3432517

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:03

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 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	12 Nov 2020 14:48:34

US3432517

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered 'VISIT3'	System	12 Nov 2020 14:48:34

US3432517

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 14:49:38

US3432517

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 14:49:38

US3432517

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '08:16'	(b) (4), (b) (6)	12 Nov 2020 14:49:38

US3432517

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered '12 Nov 2020 08:16'	System	12 Nov 2020 14:49:38

US3432517

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '97.9' F	(b) (4), (b) (6)	12 Nov 2020 14:49:38

US3432517

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Oral (Oral)'	(b) (4), (b) (6)	12 Nov 2020 14:49:38

US3432517

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 14:49:38

US3432517

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '58'	(b) (4), (b) (6)	12 Nov 2020 14:49:38

US3432517

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered 'bpm'	System	12 Nov 2020 14:49:38

US3432517

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '16'	(b) (4), (b) (6)	12 Nov 2020 14:49:38

US3432517

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered 'breaths/min'	System	12 Nov 2020 14:49:38

US3432517

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '138'	(b) (4), (b) (6)	12 Nov 2020 14:49:38

US3432517

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered 'mmHg'	System	12 Nov 2020 14:49:38

US3432517

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '74'	(b) (4), (b) (6)	12 Nov 2020 14:49:38

US3432517

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered 'mmHg'	System	12 Nov 2020 14:49:38

US3432517

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25

US3432517

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25

US3432517

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'No (N)'	(b) (4), (b) (6)	12 Nov 2020 14:49:43

US3432517

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 14:49:43

US3432517

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 14:49:58

US3432517

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 14:49:58

US3432517

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '08:35'	(b) (4), (b) (6)	12 Nov 2020 14:49:58

US3432517

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered '12 Nov 2020 08:35'	System	12 Nov 2020 14:49:58

US3432517

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 14:50:01

US3432517

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered 'I'	System	12 Nov 2020 14:50:01

US3432517

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	17 Sep 2020 15:19:14
User entered 'Day 64'	System	17 Sep 2020 15:19:14

US3432517

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-11-17T09:59:00', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '75e05ed0-9e15-42da-93da-2c4d9799d0fe'	System	17 Nov 2020 14:59:20
User entered 'No (N)'	System	17 Nov 2020 14:59:20

US3432517

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

Have you been exposed to someone with 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)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-11-17T09:59:13', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '75e05ed0-9e15-42da-93da-2c4d9799d0fe'	System	17 Nov 2020 14:59:20
User entered 'No (N)'	System	17 Nov 2020 14:59:20

US3432517

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-11-17T09:59:17', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '75e05ed0-9e15-42da-93da-2c4d9799d0fe' User entered '17 Nov 2020 09:59:17'	System	17 Nov 2020 14:59:20
	System	17 Nov 2020 14:59:20

US3432517

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	17 Sep 2020 15:19:14
User entered '17 Nov 2020 00:01'	System	17 Sep 2020 15:19:14

US3432517

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:46:10
Data entry locked.	System	17 Sep 2020 15:19:14
User entered '21 Nov 2020 23:59'	System	17 Sep 2020 15:19:14

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-11-24T09:43:41', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'c64c88b7-f188-4b2e-8d01-e36ec1c4c452'	System	24 Nov 2020 14:43:51
User entered 'No (N)'	System	24 Nov 2020 14:43:51

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

Have you been exposed to someone with 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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-11-24T09:43:44', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'c64c88b7-f188-4b2e-8d01-e36ec1c4c452'	System	24 Nov 2020 14:43:51
User entered 'No (N)'	System	24 Nov 2020 14:43:51

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-11-24T09:43:49', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'c64c88b7-f188-4b2e-8d01-e36ec1c4c452' User entered '24 Nov 2020 09:43:49'	System	24 Nov 2020 14:43:51
	System	24 Nov 2020 14:43:51

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-11-30T08:21:47', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'c25242c1-deda-4a60-b3a7-f55415fd3767'	System	30 Nov 2020 13:22:09
User entered 'No (N)'	System	30 Nov 2020 13:22:09

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

Have you been exposed to someone with 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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-11-30T08:21:55', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'c25242c1-deda-4a60-b3a7-f55415fd3767'	System	30 Nov 2020 13:22:09
User entered 'No (N)'	System	30 Nov 2020 13:22:09

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-11-30T08:22:06', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'c25242c1-deda-4a60-b3a7-f55415fd3767'	System	30 Nov 2020 13:22:09
User entered '30 Nov 2020 08:22:06'	System	30 Nov 2020 13:22:09

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-12-07T11:21:04', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '7f038d2c-67fc-433e-9170-12baaf497891'	System	07 Dec 2020 16:21:13
User entered 'No (N)'	System	07 Dec 2020 16:21:13

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

Have you been exposed to someone with 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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-12-07T11:21:08', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '7f038d2c-67fc-433e-9170-12baaf497891'	System	07 Dec 2020 16:21:13
User entered 'No (N)'	System	07 Dec 2020 16:21:13

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-12-07T11:21:11', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '7f038d2c-67fc-433e-9170-12baaf497891' User entered '07 Dec 2020 11:21:11'	System	07 Dec 2020 16:21:13
	System	07 Dec 2020 16:21:13

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-12-12T08:42:06', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '10e8f562-dd75-40da-a5fb-d3923fc1a381'	System	12 Dec 2020 13:42:29
User entered 'No (N)'	System	12 Dec 2020 13:42:29

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

Have you been exposed to someone with 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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-12-12T08:42:15', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '10e8f562-dd75-40da-a5fb-d3923fc1a381'	System	12 Dec 2020 13:42:29
User entered 'No (N)'	System	12 Dec 2020 13:42:29

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-12-12T08:42:27', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '10e8f562-dd75-40da-a5fb-d3923fc1a381' User entered '12 Dec 2020 08:42:27'	System	12 Dec 2020 13:42:29
	System	12 Dec 2020 13:42:29

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-12-19T10:06:50', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '6c616fac-4895-4593-b948-498104e39144'	System	19 Dec 2020 15:07:09
User entered 'No (N)'	System	19 Dec 2020 15:07:09

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

Have you been exposed to someone with 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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-12-19T10:06:59', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '6c616fac-4895-4593-b948-498104e39144'	System	19 Dec 2020 15:07:09
User entered 'No (N)'	System	19 Dec 2020 15:07:09

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-12-19T10:07:03', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '6c616fac-4895-4593-b948-498104e39144' User entered '19 Dec 2020 10:07:03'	System	19 Dec 2020 15:07:09
	System	19 Dec 2020 15:07:09

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-12-27T18:15:28', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'cbf9f226-a585-4782-8653-8ae432df52db' User entered 'No (N)'	System	27 Dec 2020 23:15:38
	System	27 Dec 2020 23:15:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

Have you been exposed to someone with 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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-12-27T18:15:30', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'cbf9f226-a585-4782-8653-8ae432df52db'	System	27 Dec 2020 23:15:38
User entered 'No (N)'	System	27 Dec 2020 23:15:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2020-12-27T18:15:33', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'cbf9f226-a585-4782-8653-8ae432df52db' User entered '27 Dec 2020 18:15:33'	System	27 Dec 2020 23:15:38
	System	27 Dec 2020 23:15:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-01-02T09:49:56', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '05bbfea1-f768-44d9-b488-9990bca1f8f6'	System	02 Jan 2021 14:50:09
User entered 'No (N)'	System	02 Jan 2021 14:50:09

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

Have you been exposed to someone with 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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-01-02T09:50:03', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '05bbfea1-f768-44d9-b488-9990bca1f8f6'	System	02 Jan 2021 14:50:09
User entered 'No (N)'	System	02 Jan 2021 14:50:09

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-01-02T09:50:08', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '05bbfea1-f768-44d9-b488-9990bca1f8f6' User entered '02 Jan 2021 09:50:08'	System	02 Jan 2021 14:50:09
	System	02 Jan 2021 14:50:09

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-01-12T07:07:34', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '825ba67e-b807-4ed9-aece-40704fa09880'	System	12 Jan 2021 12:07:50
User entered 'No (N)'	System	12 Jan 2021 12:07:50

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Have you been exposed to someone with 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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-01-12T07:07:43', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '825ba67e-b807-4ed9-aece-40704fa09880' User entered 'No (N)'	System	12 Jan 2021 12:07:50

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-01-12T07:07:49', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '825ba67e-b807-4ed9-aece-40704fa09880' User entered '12 Jan 2021 07:07:49'	System	12 Jan 2021 12:07:50
	System	12 Jan 2021 12:07:50

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-01-16T09:26:50', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '8e29f88d-8924-4247-b58d-346e983d711c' User entered 'No (N)'	System	16 Jan 2021 14:27:18
	System	16 Jan 2021 14:27:18

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

Have you been exposed to someone with 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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-01-16T09:27:10', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '8e29f88d-8924-4247-b58d-346e983d711c'	System	16 Jan 2021 14:27:18
User entered 'No (N)'	System	16 Jan 2021 14:27:18

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-01-16T09:27:16', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '8e29f88d-8924-4247-b58d-346e983d711c' User entered '16 Jan 2021 09:27:16'	System	16 Jan 2021 14:27:18
	System	16 Jan 2021 14:27:18

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-01-23T23:59:37', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '82539d77-ed68-475f-94a2-483187c586e4' User entered 'No (N)'	System	24 Jan 2021 04:59:49

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

Have you been exposed to someone with 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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-01-23T23:59:42', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '82539d77-ed68-475f-94a2-483187c586e4' User entered 'No (N)'	System	24 Jan 2021 04:59:49
	System	24 Jan 2021 04:59:49

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-01-23T23:59:45', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '82539d77-ed68-475f-94a2-483187c586e4' User entered '23 Jan 2021 23:59:45'	System	24 Jan 2021 04:59:49

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-01-30T09:46:59', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'e6451f2e-9eb9-4ff1-b5e9-eae4ab123ab7'	System	30 Jan 2021 14:47:14
User entered 'No (N)'	System	30 Jan 2021 14:47:14

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

Have you been exposed to someone with 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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-01-30T09:47:03', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'e6451f2e-9eb9-4ff1-b5e9-eae4ab123ab7'	System	30 Jan 2021 14:47:14
User entered 'No (N)'	System	30 Jan 2021 14:47:14

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-01-30T09:47:11', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'e6451f2e-9eb9-4ff1-b5e9-eae4ab123ab7' User entered '30 Jan 2021 09:47:11'	System	30 Jan 2021 14:47:14
	System	30 Jan 2021 14:47:14

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-02-08T20:52:50', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'b7409dda-f1cf-4e2b-a489-43b83d81311a' User entered 'Yes (Y)'	System	09 Feb 2021 01:54:05
	System	09 Feb 2021 01:54:05

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

Have you been exposed to someone with 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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-02-08T20:52:58', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'b7409dda-f1cf-4e2b-a489-43b83d81311a' User entered 'No (N)'	System	09 Feb 2021 01:54:05
	System	09 Feb 2021 01:54:05

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-02-08T20:53:04', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'b7409dda-f1cf-4e2b-a489-43b83d81311a' User entered 'No (N)'	System	09 Feb 2021 01:54:05
	System	09 Feb 2021 01:54:05

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-02-08T20:53:42', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'b7409dda-f1cf-4e2b-a489-43b83d81311a' User entered 'Yes (Y)'	System	09 Feb 2021 01:54:05
	System	09 Feb 2021 01:54:05

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Please 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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-02-08T20:53:45', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'b7409dda-f1cf-4e2b-a489-43b83d81311a'	System	09 Feb 2021 01:54:05
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Feb 2021 01:54:05

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-02-08T20:53:56', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'b7409dda-f1cf-4e2b-a489-43b83d81311a' User entered '08 Feb 2021 20:53:56'	System	09 Feb 2021 01:54:05
	System	09 Feb 2021 01:54:05

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-02-15T12:40:11', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '6deccac2-0088-4c09-b106-07a54bcd06ed' User entered 'No (N)'	System	15 Feb 2021 17:40:23
	System	15 Feb 2021 17:40:23

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

Have you been exposed to someone with 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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-02-15T12:40:14', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '6deccac2-0088-4c09-b106-07a54bcd06ed' User entered 'No (N)'	System	15 Feb 2021 17:40:23
	System	15 Feb 2021 17:40:23

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-02-15T12:40:21', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '6deccac2-0088-4c09-b106-07a54bcd06ed' User entered '15 Feb 2021 12:40:21'	System	15 Feb 2021 17:40:23
	System	15 Feb 2021 17:40:23

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-02-22T20:43:06', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'fecea9d1-e8d2-45eb-acb2-41ae49dd35c3'	System	23 Feb 2021 01:43:17
User entered 'No (N)'	System	23 Feb 2021 01:43:17

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

Have you been exposed to someone with 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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-02-22T20:43:10', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'fecea9d1-e8d2-45eb-acb2-41ae49dd35c3'	System	23 Feb 2021 01:43:17
User entered 'No (N)'	System	23 Feb 2021 01:43:17

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-02-22T20:43:13', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'fecea9d1-e8d2-45eb-acb2-41ae49dd35c3'	System	23 Feb 2021 01:43:17
User entered '22 Feb 2021 20:43:13'	System	23 Feb 2021 01:43:17

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-03-01T23:39:12-05:00', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'd9c50fd2-289b-4168-afc6-6b05c7663850'	System	02 Mar 2021 04:39:24
User entered 'No (N)'	System	02 Mar 2021 04:39:24

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

Have you been exposed to someone with 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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-03-01T23:39:17-05:00', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'd9c50fd2-289b-4168-afc6-6b05c7663850'	System	02 Mar 2021 04:39:24
User entered 'No (N)'	System	02 Mar 2021 04:39:24

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-03-01T23:39:22-05:00', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'd9c50fd2-289b-4168-afc6-6b05c7663850'	System	02 Mar 2021 04:39:24
User entered '01 Mar 2021 23:39:22'	System	02 Mar 2021 04:39:24

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-03-06T08:43:31-05:00', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'd45bf913-7507-4355-bd55-d8c26ba05a1b'	System	06 Mar 2021 13:43:52
User entered 'No (N)'	System	06 Mar 2021 13:43:52

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

Have you been exposed to someone with 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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-03-06T08:43:38-05:00', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'd45bf913-7507-4355-bd55-d8c26ba05a1b'	System	06 Mar 2021 13:43:52
User entered 'No (N)'	System	06 Mar 2021 13:43:52

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-03-06T08:43:47-05:00', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'd45bf913-7507-4355-bd55-d8c26ba05a1b' User entered '06 Mar 2021 08:43:47'	System	06 Mar 2021 13:43:52
	System	06 Mar 2021 13:43:52

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-03-13T08:21:31-05:00', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'd68add7f-2758-4d7d-b905-f78f60a69754'	System	13 Mar 2021 13:21:53
User entered 'No (N)'	System	13 Mar 2021 13:21:53

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Have you been exposed to someone with 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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-03-13T08:21:47-05:00', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'd68add7f-2758-4d7d-b905-f78f60a69754'	System	13 Mar 2021 13:21:53
User entered 'No (N)'	System	13 Mar 2021 13:21:53

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-03-13T08:21:51-05:00', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'd68add7f-2758-4d7d-b905-f78f60a69754' User entered '13 Mar 2021 08:21:51'	System	13 Mar 2021 13:21:53
	System	13 Mar 2021 13:21:53

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-03-24T11:59:18-04:00', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '4fb7ce64-685c-4f56-b379-fe4d936b7c0c'	System	24 Mar 2021 15:59:28
User entered 'No (N)'	System	24 Mar 2021 15:59:28

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

Have you been exposed to someone with 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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-03-24T11:59:21-04:00', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '4fb7ce64-685c-4f56-b379-fe4d936b7c0c'	System	24 Mar 2021 15:59:28
User entered 'No (N)'	System	24 Mar 2021 15:59:28

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-03-24T11:59:24-04:00', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '4fb7ce64-685c-4f56-b379-fe4d936b7c0c' User entered '24 Mar 2021 11:59:24'	System	24 Mar 2021 15:59:28
	System	24 Mar 2021 15:59:28

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-03-27T18:07:56-04:00', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'f984dbd4-5989-4e65-b8b3-a52bd53c4f22'	System	30 Mar 2021 23:36:57
User entered 'No (N)'	System	30 Mar 2021 23:36:57

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Have you been exposed to someone with 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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-03-27T18:07:59-04:00', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'f984dbd4-5989-4e65-b8b3-a52bd53c4f22'	System	30 Mar 2021 23:36:57
User entered 'No (N)'	System	30 Mar 2021 23:36:57

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-03-27T18:08:02-04:00', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'f984dbd4-5989-4e65-b8b3-a52bd53c4f22'	System	30 Mar 2021 23:36:57
User entered '27 Mar 2021 18:08:02'	System	30 Mar 2021 23:36:57

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-04-05T12:14:32-04:00', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '683fad7a-4d77-4ccc-8da5-4a99a0d7cda5'	System	05 Apr 2021 16:18:43
User entered 'No (N)'	System	05 Apr 2021 16:18:43

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

Have you been exposed to someone with 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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-04-05T12:14:35-04:00', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '683fad7a-4d77-4ccc-8da5-4a99a0d7cda5'	System	05 Apr 2021 16:18:43
User entered 'No (N)'	System	05 Apr 2021 16:18:43

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-04-05T12:14:37-04:00', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '683fad7a-4d77-4ccc-8da5-4a99a0d7cda5' User entered '05 Apr 2021 12:14:37'	System	05 Apr 2021 16:18:43
	System	05 Apr 2021 16:18:43

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-04-11T08:31:31-04:00', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '753a66a9-f89f-4d4e-b917-9a6455a1c9cf' User entered 'No (N)'	System	11 Apr 2021 12:31:42

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

Have you been exposed to someone with 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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-04-11T08:31:35-04:00', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '753a66a9-f89f-4d4e-b917-9a6455a1c9cf' User entered 'No (N)'	System	11 Apr 2021 12:31:42

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-04-11T08:31:40-04:00', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '753a66a9-f89f-4d4e-b917-9a6455a1c9cf'	System	11 Apr 2021 12:31:42
User entered '11 Apr 2021 08:31:40'	System	11 Apr 2021 12:31:42

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-04-19T23:27:47-04:00', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '91c1c085-a1d1-468d-9899-a85c676f8ca9' User entered 'No (N)'	System	20 Apr 2021 03:28:02
	System	20 Apr 2021 03:28:02

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

Have you been exposed to someone with 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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-04-19T23:27:52-04:00', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '91c1c085-a1d1-468d-9899-a85c676f8ca9' User entered 'No (N)'	System	20 Apr 2021 03:28:02
	System	20 Apr 2021 03:28:02

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-04-19T23:27:55-04:00', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '91c1c085-a1d1-468d-9899-a85c676f8ca9' User entered '19 Apr 2021 23:27:55'	System	20 Apr 2021 03:28:02
	System	20 Apr 2021 03:28:02

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-04-25T01:39:54-04:00', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '413d6dcd-5567-4b9a-babe-bc8746bc2e9e'	System	03 May 2021 02:15:39
User entered 'No (N)'	System	03 May 2021 02:15:39

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

Have you been exposed to someone with 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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-04-25T01:40:00-04:00', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '413d6dcd-5567-4b9a-babe-bc8746bc2e9e'	System	03 May 2021 02:15:39
User entered 'No (N)'	System	03 May 2021 02:15:39

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-04-25T01:40:10-04:00', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: '413d6dcd-5567-4b9a-babe-bc8746bc2e9e' User entered '25 Apr 2021 01:40:10'	System	03 May 2021 02:15:39
	System	03 May 2021 02:15:39

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-05-02T22:15:36-04:00', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'b58eb9b9-f97b-4417-a48e-2d4e2d6a7a18'	System	03 May 2021 02:15:47
User entered 'No (N)'	System	03 May 2021 02:15:47

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

Have you been exposed to someone with 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 (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-05-02T22:15:40-04:00', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'b58eb9b9-f97b-4417-a48e-2d4e2d6a7a18'	System	03 May 2021 02:15:47
User entered 'No (N)'	System	03 May 2021 02:15:47

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-05-02T22:15:44-04:00', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'b58eb9b9-f97b-4417-a48e-2d4e2d6a7a18'	System	03 May 2021 02:15:47
User entered '02 May 2021 22:15:44'	System	03 May 2021 02:15:47

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '29 Oct 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '02 Nov 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '05 Nov 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '09 Nov 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '12 Nov 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '16 Nov 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '19 Nov 2022 00:01'	System	20 Nov 2020 09:10:38

US3432517

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:40:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 09:10:38
Amendment Manager: User entered '23 Nov 2022 23:59'	System	20 Nov 2020 09:10:38

US3432517

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:40:03

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:00:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-03-01T23:51:17-05:00', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'c3d360ab-3005-4ad9-a6a1-97c4af2da402'	System	06 Mar 2021 13:43:30
User entered 'No (N)'	System	06 Mar 2021 13:43:30

US3432517

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:40:03

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 06:00:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (300C77A0-840E-4869-A73D-41954BDDD8BD)', Time: '2021-03-01T23:51:20-05:00', User OID: 'PatientReportedOutcome (US3432517)', ODM File OID: 'c3d360ab-3005-4ad9-a6a1-97c4af2da402'	System	06 Mar 2021 13:43:30
User entered '01 Mar 2021 23:51:20'	System	06 Mar 2021 13:43:30

US3432517

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	07 Dec 2020 19:08:54

US3432517

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '7 Dec 2020'	Kathleen Garvey (b) (4)	07 Dec 2020 19:08:54

US3432517

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Contact Made (CONTACT MADE)'	Kathleen Garvey (b) (4)	07 Dec 2020 19:08:54

US3432517

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered empty.	Kathleen Garvey (b) (4)	07 Dec 2020 19:08:54

US3432517

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	07 Dec 2020 19:09:02

US3432517

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 03:35:25
User entered 'I'	System	07 Dec 2020 19:09:02

US3432517

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:38:35
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	12 Jan 2021 17:14:40

US3432517

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:38:35
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '12 Jan 2021'	Kathleen Garvey (b) (4)	12 Jan 2021 17:14:40

US3432517

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:38:35
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Contact Made (CONTACT MADE)'	Kathleen Garvey (b) (4)	12 Jan 2021 17:14:40

US3432517

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:38:35
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered empty.	Kathleen Garvey (b) (4)	12 Jan 2021 17:14:40

US3432517

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:38:35
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	12 Jan 2021 17:14:53

US3432517

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:38:35
User entered 'I'	System	12 Jan 2021 17:14:53

US3432517

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:38:35
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered 'Yes (Y)'	Austin Kim (b) (4)	31 Mar 2021 21:32:33

US3432517

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:38:35
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered '09 Feb 2021'	Austin Kim (b) (4)	31 Mar 2021 21:32:33

US3432517

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:38:35
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered 'Contact Made (CONTACT MADE)'	Austin Kim (b) (4)	31 Mar 2021 21:32:33

US3432517

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:38:35
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered empty.	Austin Kim (b) (4)	31 Mar 2021 21:32:33

US3432517

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:38:35
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered 'Yes (Y)'	Bethany Evans (b) (4)	15 Mar 2021 19:17:00

US3432517

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:38:35
User entered 'I'	System	15 Mar 2021 19:17:00

US3432517

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:38:35
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered 'Yes (Y)'	Bethany Evans (b) (4)	15 Mar 2021 19:17:10

US3432517

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:38:35
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered '15 Mar 2021'	Bethany Evans (b) (4)	15 Mar 2021 19:17:10

US3432517

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:38:35
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered 'Contact Made (CONTACT MADE)'	Bethany Evans (b) (4)	15 Mar 2021 19:17:10

US3432517

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:38:35
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered empty.	Bethany Evans (b) (4)	15 Mar 2021 19:17:10

US3432517

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:38:35
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered 'Yes (Y)'	Bethany Evans (b) (4)	15 Mar 2021 19:17:16

US3432517

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 06:38:35
User entered 'I'	System	15 Mar 2021 19:17:16

US3432517

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:24:43
User entered 'Yes (Y)'	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 12:53:23

US3432517

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:24:43
User entered '13 Apr 2021'	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 12:53:23

US3432517

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:03

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:24:43
User entered 'Clinic (Clinic)'	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 12:53:23

US3432517

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:03

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	13 Apr 2021 12:53:23

US3432517

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:24:43
User entered 'Yes (Y)'	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 12:54:03

US3432517

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:24:43
User entered '13 Apr 2021'	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 12:54:03

US3432517

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:24:43
User entered '08:23'	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 12:54:03

US3432517

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
User entered '13 Apr 2021 08:23'	System	13 Apr 2021 12:54:03

US3432517

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:24:43
User entered '36.5' C	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 12:54:03

US3432517

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:24:43
User entered 'Oral (Oral)'	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 12:54:03

US3432517

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:24:43
User entered empty.	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 12:54:03

US3432517

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:24:43
User entered '62'	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 12:54:03

US3432517

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Apr 2021 12:54:03

US3432517

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:24:43
User entered '12'	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 12:54:03

US3432517

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Apr 2021 12:54:03

US3432517

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:24:43
User entered '139'	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 12:54:03

US3432517

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Apr 2021 12:54:03

US3432517

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:24:43
User entered '80'	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 12:54:03

US3432517

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Apr 2021 12:54:03

US3432517

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:24:43
User entered 'No (N)'	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 12:54:37

US3432517

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:24:43
User entered empty.	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 12:54:37

US3432517

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:24:43
User entered 'Yes (Y)'	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 12:55:24

US3432517

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:24:43
User entered '13 Apr 2021'	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 12:55:24

US3432517

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:03

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:24:43
User entered '08:33'	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 12:55:24

US3432517

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
User entered '13 Apr 2021 08:33'	System	13 Apr 2021 12:55:24

US3432517

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:24:43
User entered 'Yes (Y)'	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 12:56:27

US3432517

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:03

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 12:56:27

US3432517

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

Form: Visit Date

Generated On: 09 Jun 2021 17:40:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	Monica Feeley (b) (4)	09 Feb 2021 22:21:07

US3432517

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

Form: Visit Date

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '9 Feb 2021'	Monica Feeley (b) (4)	09 Feb 2021 22:21:07

US3432517

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

Form: Visit Date

Generated On: 09 Jun 2021 17:40:03

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Clinic (Clinic)'	Monica Feeley (b) (4)	09 Feb 2021 22:21:07

US3432517

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

Form: Visit Date

Generated On: 09 Jun 2021 17:40:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered 'UNBLND_DECIDE'	System	09 Feb 2021 22:21:07

US3432517

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:03

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '9 Feb 2021'	Monica Feeley (b) (4)	09 Feb 2021 22:23:31

US3432517

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:03

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:13:04

US3432517

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:03

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	Monica Feeley (b) (4)	09 Feb 2021 22:23:31

US3432517

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:03

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 09:13:04

US3432517

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:03

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '9 Feb 2021'	Monica Feeley (b) (4)	09 Feb 2021 22:23:31

US3432517

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:03

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Placebo (Placebo)'	Monica Feeley (b) (4)	09 Feb 2021 22:23:31

US3432517

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:03

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Placebo (Placebo)'	Monica Feeley (b) (4)	09 Feb 2021 22:23:31

US3432517

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:03

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Placebo (Placebo)'	Monica Feeley (b) (4)	09 Feb 2021 22:23:31

US3432517

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:03

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	Monica Feeley (b) (4)	09 Feb 2021 22:23:31

US3432517

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:03

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered '1'	System	09 Feb 2021 22:23:31

US3432517

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

Form: Unblinding

Generated On: 09 Jun 2021 17:40:03

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered 'I'	System	09 Feb 2021 22:23:31

US3432517

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:03

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered missing code ND - Not Done.	Monica Feeley (b) (4)	09 Feb 2021 22:27:24

US3432517

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered missing code ND - Not Done.	Monica Feeley (b) (4)	09 Feb 2021 22:27:24

US3432517

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:03

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered empty.	System	09 Feb 2021 22:27:24
DataPoint set to visible.	System	09 Feb 2021 22:23:31

US3432517

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:03

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered missing code ND - Not Done.	Monica Feeley (b) (4)	09 Feb 2021 22:27:24

US3432517

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered missing code ND - Not Done.	Monica Feeley (b) (4)	09 Feb 2021 22:27:24

US3432517

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:03

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered empty.	System	09 Feb 2021 22:27:24
DataPoint set to visible.	System	09 Feb 2021 22:23:31

US3432517

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User accepted default value 'Pre-Dose (PREDOSE)'	Monica Feeley (b) (4) (b) (4)	09 Feb 2021 22:27:24

US3432517

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	Monica Feeley (b) (4)	09 Feb 2021 22:27:24

US3432517

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '9 Feb 2021'	Monica Feeley (b) (4)	09 Feb 2021 22:27:24

US3432517

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '10:20'	Monica Feeley (b) (4)	09 Feb 2021 22:27:24

US3432517

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered '9 Feb 2021 10:20'	System	09 Feb 2021 22:27:24

US3432517

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '98.0' F	Monica Feeley (b) (4)	09 Feb 2021 22:27:24

US3432517

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Oral (Oral)'	Monica Feeley (b) (4)	09 Feb 2021 22:27:24

US3432517

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered empty.	Monica Feeley (b) (4)	09 Feb 2021 22:27:24

US3432517

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '056'	Monica Feeley (b) (4)	09 Feb 2021 22:27:24

US3432517

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered 'bpm'	System	09 Feb 2021 22:27:24

US3432517

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '012'	Monica Feeley (b) (4)	09 Feb 2021 22:27:24

US3432517

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered 'breaths/min'	System	09 Feb 2021 22:27:24

US3432517

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '165'	Monica Feeley (b) (4)	09 Feb 2021 22:27:24

US3432517

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered 'mmHg'	System	09 Feb 2021 22:27:24

US3432517

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '095'	Monica Feeley (b) (4)	09 Feb 2021 22:27:24

US3432517

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered 'mmHg'	System	09 Feb 2021 22:27:24

US3432517

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:03

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered missing code ND - Not Done.	Monica Feeley (b) (4)	09 Feb 2021 22:27:24

US3432517

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered missing code ND - Not Done.	Monica Feeley (b) (4)	09 Feb 2021 22:27:24

US3432517

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:40:03

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered empty.	System	09 Feb 2021 22:27:24
DataPoint set to visible.	System	09 Feb 2021 22:23:31

US3432517

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User accepted default value 'Post-Dose (POSTDOSE)'	Monica Feeley (b) (4) (b) (4)	09 Feb 2021 22:27:24

US3432517

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	Monica Feeley (b) (4)	09 Feb 2021 22:27:24

US3432517

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '9 Feb 2021'	Monica Feeley (b) (4)	09 Feb 2021 22:27:24

US3432517

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '11:53'	Monica Feeley (b) (4)	09 Feb 2021 22:27:24

US3432517

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered '9 Feb 2021 11:53'	System	09 Feb 2021 22:27:24

US3432517

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '97.5' F	Monica Feeley (b) (4)	09 Feb 2021 22:27:24

US3432517

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Other (Other)'	Monica Feeley (b) (4)	09 Feb 2021 22:27:24

US3432517

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'IR'	Monica Feeley (b) (4)	09 Feb 2021 22:27:24

US3432517

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '055'	Monica Feeley (b) (4)	09 Feb 2021 22:27:24

US3432517

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered 'bpm'	System	09 Feb 2021 22:27:24

US3432517

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '014'	Monica Feeley (b) (4)	09 Feb 2021 22:27:24

US3432517

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered 'breaths/min'	System	09 Feb 2021 22:27:24

US3432517

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '169'	Monica Feeley (b) (4)	09 Feb 2021 22:27:24

US3432517

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered 'mmHg'	System	09 Feb 2021 22:27:24

US3432517

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '097'	Monica Feeley (b) (4)	09 Feb 2021 22:27:24

US3432517

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered 'mmHg'	System	09 Feb 2021 22:27:24

US3432517

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	Monica Feeley (b) (4)	09 Feb 2021 22:23:46

US3432517

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

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '9 Feb 2021'	Monica Feeley (b) (4)	09 Feb 2021 22:23:46

US3432517

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

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	Monica Feeley (b) (4)	09 Feb 2021 22:24:29

US3432517

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

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered empty.	Monica Feeley (b) (4)	09 Feb 2021 22:24:29

US3432517

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

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered empty.	Monica Feeley (b) (4)	09 Feb 2021 22:24:29

US3432517

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

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered 'mRNA-1273'	System	09 Feb 2021 22:24:29
DataPoint set to visible.	System	09 Feb 2021 22:23:31

US3432517

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

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '9 Feb 2021'	Monica Feeley (b) (4)	09 Feb 2021 22:24:29

US3432517

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

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '11:22'	Monica Feeley (b) (4)	09 Feb 2021 22:24:29

US3432517

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

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered '9 Feb 2021 11:22'	System	09 Feb 2021 22:24:29

US3432517

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

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Left Arm (LEFT ARM)'	Monica Feeley (b) (4)	09 Feb 2021 22:24:29

US3432517

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

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered 'ONCE'	System	09 Feb 2021 22:24:29

US3432517

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

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered 'INTRAMUSCULAR'	System	09 Feb 2021 22:24:29

US3432517

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	Monica Feeley (b) (4)	09 Feb 2021 22:44:32

US3432517

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '9 Feb 2021'	Monica Feeley (b) (4)	09 Feb 2021 22:44:32

US3432517

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '10:29'	Monica Feeley (b) (4)	09 Feb 2021 22:44:32

US3432517

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered '9 Feb 2021 10:29'	System	09 Feb 2021 22:44:32

US3432517

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:40:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	Monica Feeley (b) (4)	09 Feb 2021 22:44:42

US3432517

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:40:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '9 Feb 2021'	Monica Feeley (b) (4)	09 Feb 2021 22:44:42

US3432517

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:40:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '10:30'	Monica Feeley (b) (4)	09 Feb 2021 22:44:42

US3432517

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:40:03

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered '9 Feb 2021 10:30'	System	09 Feb 2021 22:44:42

US3432517

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

Form: Continuing

Generated On: 09 Jun 2021 17:40:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Feb 2021 20:25:45

US3432517

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

Form: Continuing

Generated On: 09 Jun 2021 17:40:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered 'I'	System	17 Feb 2021 20:25:45

US3432517

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Feb 2021 20:26:02

US3432517

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '17 Feb 2021'	(b) (4), (b) (6)	17 Feb 2021 20:26:02

US3432517

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Feb 2021 20:26:02

US3432517

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered empty.	(b) (4), (b) (6)	17 Feb 2021 20:26:02

US3432517

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Feb 2021 20:25:53

US3432517

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered 'I'	System	17 Feb 2021 20:25:53

US3432517

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:03

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered '1'	System	17 Feb 2021 20:25:53
DataPoint set to visible.	System	17 Feb 2021 20:25:53

US3432517

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 15:48:13

US3432517

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered '8 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 15:51:23
User entered '9 Mar 2021'	(b) (4), (b) (6)	09 Mar 2021 15:48:13

US3432517

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	09 Mar 2021 15:48:13

US3432517

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered 'OLD29'	System	09 Mar 2021 15:48:13

US3432517

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	09 Mar 2021 15:50:20

US3432517

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 15:50:20

US3432517

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	09 Mar 2021 15:51:36
User entered '8 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 15:51:36
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	09 Mar 2021 15:51:23
User entered '9 Mar 2021'	(b) (4), (b) (6)	09 Mar 2021 15:50:20

US3432517

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User closed query 'Data is required. Please provide.' (Site from System).	System	09 Mar 2021 15:50:37
Query 'Data is required. Please provide.' answered by System data change (Site from System).		09 Mar 2021 15:50:37
User entered '15:10' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 15:50:37
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Mar 2021 15:50:20
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 15:50:20

US3432517

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered '8 Mar 2021 15:10'	System	09 Mar 2021 15:51:36
User entered '9 Mar 2021 15:10'	System	09 Mar 2021 15:50:37
User entered empty.	System	09 Mar 2021 15:50:20

US3432517

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User closed query 'Data is required. Please provide.' (Site from System).	System	09 Mar 2021 15:50:59
Query 'Data is required. Please provide.' answered by System data change (Site from System).		09 Mar 2021 15:50:59
User entered '36.7' C reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 15:50:59
User opened query 'Data is required. Please provide.' (Site from System).	System	09 Mar 2021 15:50:20
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 15:50:20

US3432517

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 15:50:59
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 15:50:20

US3432517

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 15:50:20

US3432517

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered '061'	(b) (4), (b) (6)	09 Mar 2021 15:50:20

US3432517

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered 'bpm'	System	09 Mar 2021 15:50:20

US3432517

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered '14'	(b) (4), (b) (6)	09 Mar 2021 15:50:20

US3432517

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered 'breaths/min'	System	09 Mar 2021 15:50:20

US3432517

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered '155'	(b) (4), (b) (6)	09 Mar 2021 15:50:20

US3432517

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered 'mmHg'	System	09 Mar 2021 15:50:20

US3432517

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered '085'	(b) (4), (b) (6)	09 Mar 2021 15:50:20

US3432517

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:40:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered 'mmHg'	System	09 Mar 2021 15:50:20

US3432517

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	09 Mar 2021 15:50:20

US3432517

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 15:50:20

US3432517

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	09 Mar 2021 15:51:36
User entered '8 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 15:51:36
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	09 Mar 2021 15:51:23
User entered '9 Mar 2021'	(b) (4), (b) (6)	09 Mar 2021 15:50:20

US3432517

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered '16:06'	(b) (4), (b) (6)	09 Mar 2021 15:50:20

US3432517

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered '8 Mar 2021 16:06'	System	09 Mar 2021 15:51:36
User entered '9 Mar 2021 16:06'	System	09 Mar 2021 15:50:20

US3432517

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered '36.8' C	(b) (4), (b) (6)	09 Mar 2021 15:50:20

US3432517

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered 'Oral (Oral)'	(b) (4), (b) (6)	09 Mar 2021 15:50:20

US3432517

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 15:50:20

US3432517

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered '048'	(b) (4), (b) (6)	09 Mar 2021 15:50:20

US3432517

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered 'bpm'	System	09 Mar 2021 15:50:20

US3432517

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered '14'	(b) (4), (b) (6)	09 Mar 2021 15:50:20

US3432517

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered 'breaths/min'	System	09 Mar 2021 15:50:20

US3432517

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered '159'	(b) (4), (b) (6)	09 Mar 2021 15:50:20

US3432517

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered 'mmHg'	System	09 Mar 2021 15:50:20

US3432517

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered '089'	(b) (4), (b) (6)	09 Mar 2021 15:50:20

US3432517

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:40:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered 'mmHg'	System	09 Mar 2021 15:50:20

US3432517

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 15:51:13

US3432517

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User closed query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	09 Mar 2021 15:51:23
User opened query 'The Physical Examination Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	System	09 Mar 2021 15:51:13
User entered '8 Mar 2021'	(b) (4), (b) (6)	09 Mar 2021 15:51:13

US3432517

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 15:52:06

US3432517

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 15:52:06

US3432517

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 15:52:06

US3432517

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered 'mRNA-1273'	System	09 Mar 2021 15:52:06
DataPoint set to visible.	System	17 Feb 2021 20:25:53

US3432517

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered '8 Mar 2021'	(b) (4), (b) (6)	09 Mar 2021 15:52:06

US3432517

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered '15:32'	(b) (4), (b) (6)	09 Mar 2021 15:52:06

US3432517

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered '8 Mar 2021 15:32'	System	09 Mar 2021 15:52:06

US3432517

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	09 Mar 2021 15:52:06

US3432517

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered 'ONCE'	System	09 Mar 2021 15:52:06

US3432517

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:40:03

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered 'INTRAMUSCULAR'	System	09 Mar 2021 15:52:06

US3432517

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 15:52:15

US3432517

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered 'I'	System	09 Mar 2021 15:52:15

US3432517

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:32
User entered 'Yes (Y)'	Bethany Evans (b) (4)	15 Mar 2021 19:16:24

US3432517

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:32
User entered '15 Mar 2021'	Bethany Evans (b) (4)	15 Mar 2021 19:16:24

US3432517

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:32
User entered 'Contact Made (CONTACT MADE)'	Bethany Evans (b) (4)	15 Mar 2021 19:16:24

US3432517

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:40:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:32
User entered empty.	Bethany Evans (b) (4)	15 Mar 2021 19:16:24

US3432517

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:10:32
User entered 'Yes (Y)'	Bethany Evans (b) (4)	15 Mar 2021 19:16:29

US3432517

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:40:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:49:49
User entered 'I'	System	15 Mar 2021 19:16:29

US3432517

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:24:43
User entered 'Yes (Y)'	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 12:57:00

US3432517

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:24:43
User entered '13 Apr 2021'	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 12:57:00

US3432517

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:03

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:24:43
User entered 'Clinic (Clinic)'	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 12:57:00

US3432517

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:40:03

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	13 Apr 2021 12:57:00

US3432517

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:24:43
User entered 'Yes (Y)'	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 12:57:35

US3432517

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:24:43
User entered '13 Apr 2021'	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 12:57:35

US3432517

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:24:43
User entered '08:23'	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 12:57:35

US3432517

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
User entered '13 Apr 2021 08:23'	System	13 Apr 2021 12:57:35

US3432517

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:24:43
User entered '36.5' C	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 12:57:35

US3432517

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:24:43
User entered 'Oral (Oral)'	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 12:57:35

US3432517

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:24:43
User entered empty.	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 12:57:35

US3432517

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:24:43
User entered '62'	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 12:57:35

US3432517

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Apr 2021 12:57:35

US3432517

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:24:43
User entered '12'	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 12:57:35

US3432517

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Apr 2021 12:57:35

US3432517

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:24:43
User entered '139'	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 12:57:35

US3432517

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Apr 2021 12:57:35

US3432517

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:24:43
User entered '80'	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 12:57:35

US3432517

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:40:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Apr 2021 12:57:35

US3432517

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Apr 2021 12:57:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Apr 2021 12:57:41

US3432517

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:40:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User closed query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	13 Apr 2021 12:57:45
User opened query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	System	13 Apr 2021 12:57:41
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 12:57:41

US3432517

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:24:43
User entered 'Yes (Y)'	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 12:58:00

US3432517

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:24:43
User entered '13 Apr 2021'	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 12:58:00

US3432517

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:24:43
User entered '08:33'	(b) (4), (b) (6) [REDACTED]	13 Apr 2021 12:58:00

US3432517

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
User entered '13 Apr 2021 08:33'	System	13 Apr 2021 12:58:00

US3432517

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:40:03

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:58:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:24
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	22 Oct 2020 16:08:45

US3432517

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:03

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:54

US3432517

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:03

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Dizziness, LLT: Lightheadedness - version MedDRA\\23.0.	Coder Import (b) (4)	22 Oct 2020 16:11:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Oct 2020 16:11:44
Data point term sent to Coder	System	22 Oct 2020 16:10:08
User entered 'lightheadedness'	Xhoi Mitre (b) (4)	22 Oct 2020 16:09:49

US3432517

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered 'No (N)'	Xhoi Mitre (b) (4)	22 Oct 2020 16:09:49

US3432517

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered 'No (N)'	Xhoi Mitre (b) (4)	22 Oct 2020 16:09:49

US3432517

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered 'No (N)'	Xhoi Mitre (b) (4)	22 Oct 2020 16:09:49

US3432517

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered '15 Oct 2020'	Xhoi Mitre (b) (4)	22 Oct 2020 16:09:49

US3432517

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:03

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered '13:00'	Xhoi Mitre (b) (4)	22 Oct 2020 16:09:49

US3432517

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:54
User entered '15 Oct 2020 13:00'	System	22 Oct 2020 16:09:49

US3432517

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered 'No (N)'	Xhoi Mitre (b) (4)	22 Oct 2020 16:09:49

US3432517

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered '15 Oct 2020'	Xhoi Mitre (b) (4)	22 Oct 2020 16:09:49

US3432517

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:03

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered '19:00'	Xhoi Mitre (b) (4)	22 Oct 2020 16:09:49

US3432517

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:54
User entered '15 Oct 2020 19:00'	System	22 Oct 2020 16:09:49

US3432517

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:03

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered 'Grade 1/Mild (Grade 1/Mild)'	Xhoi Mitre (b) (4)	22 Oct 2020 16:09:49

US3432517

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered 'No (N)'	Xhoi Mitre (b) (4)	22 Oct 2020 16:09:49

US3432517

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:03

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered '0'	Xhoi Mitre (b) (4)	22 Oct 2020 16:09:49

US3432517

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:03

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered '0'	Xhoi Mitre (b) (4)	22 Oct 2020 16:09:49

US3432517

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered '0'	Xhoi Mitre (b) (4)	22 Oct 2020 16:09:49

US3432517

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered empty.	Xhoi Mitre (b) (4)	22 Oct 2020 16:09:49

US3432517

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:03

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered empty.	Xhoi Mitre (b) (4)	22 Oct 2020 16:09:49

US3432517

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered empty.	Xhoi Mitre (b) (4)	22 Oct 2020 16:09:49

US3432517

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered empty.	Xhoi Mitre (b) (4)	22 Oct 2020 16:09:49

US3432517

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered '0'	Xhoi Mitre (b) (4)	22 Oct 2020 16:09:49

US3432517

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered '0'	Xhoi Mitre (b) (4)	22 Oct 2020 16:09:49

US3432517

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:03

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered '0'	Xhoi Mitre (b) (4)	22 Oct 2020 16:09:49

US3432517

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered 'Related (RELATED)'	Xhoi Mitre (b) (4)	22 Oct 2020 16:09:49

US3432517

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered 'Related (RELATED)'	Xhoi Mitre (b) (4)	22 Oct 2020 16:09:49

US3432517

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:03

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered 'None (NONE)'	Xhoi Mitre (b) (4)	22 Oct 2020 16:09:49

US3432517

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:03

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered 'I'	Xhoi Mitre (b) (4)	22 Oct 2020 16:09:49

US3432517

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered '0'	Xhoi Mitre (b) (4)	22 Oct 2020 16:09:49

US3432517

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered '0'	Xhoi Mitre (b) (4)	22 Oct 2020 16:09:49

US3432517

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:03

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Xhoi Mitre (b) (4)	22 Oct 2020 16:09:49

US3432517

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:03

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 13:43:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered empty.	Xhoi Mitre (b) (4)	22 Oct 2020 16:09:49

US3432517

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:03

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:54
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered empty.	Xhoi Mitre (b) (4)	22 Oct 2020 16:09:49

US3432517

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:03

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:54
User entered '0'	System	22 Oct 2020 16:09:49

US3432517

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:03

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:54
User entered '0'	System	22 Oct 2020 16:09:49

US3432517

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:40:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 13:43:54

US3432517

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:03

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:29:05

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:03

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:29:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User closed query 'Per DM CLR: Please provide the specific location of muscle pain (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 13:05:43
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLT: Muscle pains, PT: Myalgia, LLT: Myalgia - version MedDRA\\23.0.	Coder Import (b) (4)	07 Apr 2021 23:20:30
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	07 Apr 2021 23:20:30
Data point term sent to Coder	System	07 Apr 2021 23:19:35
Query 'Per DM CLR: Please provide the specific location of muscle pain (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'updated' (Site from DM).	Jessica Cauley (b) (4)	07 Apr 2021 23:19:02
Coding entries removed.	Jessica Cauley (b) (4)	07 Apr 2021 23:18:44
User entered 'generalized MYALGIAS' reason for change: Data Entry Error	Jessica Cauley (b) (4)	07 Apr 2021 23:18:44
User opened query 'Per DM CLR: Please provide the specific location of muscle pain (eg, generalized myalgia, back muscle pain, arms, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 01:46:44
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLT: Muscle pains, PT: Myalgia, LLT: Myalgia - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 22:29:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	23 Oct 2020 22:29:39
Data point term sent to Coder	System	23 Oct 2020 22:28:30

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:03

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'myalgias'	Phoebe Cunningham (b) (4)	23 Oct 2020 22:28:21

US3432517

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:29:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered 'No (N)'	Phoebe Cunningham (b) (4)	23 Oct 2020 22:28:21

US3432517

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:29:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User closed query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 04:44:27
Query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify.' answered with 'this lasted more than 7 days post injection therefore meets AE reporting criteria. updated to YES' (Site from DM).	Jessica Cauley (b) (4)	04 Jan 2021 21:18:44
User entered 'Yes (Y)' reason for change: Per Query Resolution	(b) (4)	04 Jan 2021 21:18:05
User opened query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Dec 2020 10:03:59
User entered 'No (N)'	Phoebe Cunningham (b) (4)	23 Oct 2020 22:28:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:29:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered 'No (N)'	Phoebe Cunningham (b) (4)	23 Oct 2020 22:28:21

US3432517

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:29:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User closed query 'Per DM CLR: RQ: Response noted, however, subject first felt this symptom on 15 OCT 2020 per eDiary. Please review and reconcile the date as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 13:05:50
Query 'Per DM CLR: RQ: Response noted, however, subject first felt this symptom on 15 OCT 2020 per eDiary. Please review and reconcile the date as appropriate. Otherwise, clarify.' answered with 'Start date updated to 15OCT2020 because symptoms was first reported on this date.' (Site from DM).	Austin Kim (b) (4)	07 Apr 2021 23:38:09
User entered '15 Oct 2020' reason for change: Data Entry Error	Austin Kim (b) (4)	07 Apr 2021 23:36:58
User opened query 'Per DM CLR: RQ: Response noted, however, subject first felt this symptom on 15 OCT 2020 per eDiary. Please review and reconcile the date as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 01:48:31
User closed query 'Per CDM re-query: PC time stamp for Muscle ache is recorded on 15 OCT in eDiary. If the solicited event continue beyond day 7 post vaccination, the AE should be recorded with the start date as recorded per eDiary (15 OCT). Please review and update accordingly else clarify in query response.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 09:01:20
Query 'Per CDM re-query: PC time stamp for Muscle ache is recorded on 15 OCT in eDiary. If the solicited event continue beyond day 7 post vaccination, the AE should be recorded with the start date as recorded per eDiary (15 OCT). Please review and update accordingly else clarify in query response.' answered with 'no muscle aches reported 18oct 19oct therefore the start date for this ae is 20oct' (Site from DM).	Jessica Cauley (b) (4)	17 Mar 2021 13:23:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom MUSCLE ACHES on 15OCT2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 05:53:25
User opened query 'Per CDM re-query: PC time stamp for Muscle ache is recorded on 15 OCT in eDiary. If the solicited event continue beyond day 7 post vaccination, the AE should be recorded with the start date as recorded per eDiary (15 OCT). Please review and update accordingly else clarify in query response. ' (Site from DM).	(b) (4), (b) (6)	11 Mar 2021 05:53:23
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom MUSCLE ACHES on 15OCT2020. Please review if this should be reconciled. Else, provide clarification on dates.' answered with 'the period of myalgias that extended beyond reacto period began 20oct. ' (Site from DM).	Jessica Cauley (b) (4) (b) (4)	10 Mar 2021 15:56:15
User entered '20 Oct 2020' reason for change: Data Entry Error	Jessica Cauley (b) (4) (b) (4)	10 Mar 2021 15:55:30
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom MUSCLE ACHES on 15OCT2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	20 Dec 2020 10:04:05
User entered '22 Oct 2020'	Phoebe Cunningham (b) (4)	23 Oct 2020 22:28:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:03

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:29:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Apr 2021 23:38:16
User entered '23:11' reason for change: Data Entry Error	Austin Kim (b) (4)	07 Apr 2021 23:38:16
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Apr 2021 23:37:07
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Apr 2021 23:37:07
User entered 'un:un' (non-conformant).	Austin Kim (b) (4)	07 Apr 2021 23:37:07
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Apr 2021 23:36:58
User entered empty.	Phoebe Cunningham (b) (4)	23 Oct 2020 22:28:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:29:05
User entered '15 Oct 2020 23:11'	System	07 Apr 2021 23:38:16
User entered '15 Oct 2020 UN:UN' (non-conformant).	System	07 Apr 2021 23:37:07
User entered empty.	System	23 Oct 2020 22:28:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:29:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered 'No (N)'	Phoebe Cunningham (b) (4)	23 Oct 2020 22:28:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:03

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:29:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered '23 Oct 2020'	Phoebe Cunningham (b) (4)	23 Oct 2020 22:28:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:03

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:29:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	13 Apr 2021 12:32:47
Query 'Data is required. Please provide.' answered with 'time is unknown' (Site from System).	Austin Kim (b) (4)	07 Apr 2021 23:39:00
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Apr 2021 23:38:53
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Apr 2021 23:38:53
User entered empty; reason for change Data Entry Error	Austin Kim (b) (4)	07 Apr 2021 23:38:53
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Apr 2021 23:38:32
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Apr 2021 23:38:32
User entered 'Un:UN' (non-conformant).	Austin Kim (b) (4)	07 Apr 2021 23:38:32
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Apr 2021 23:36:58
User entered empty.	Phoebe Cunningham (b) (4)	23 Oct 2020 22:28:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:29:05
User entered empty.	System	07 Apr 2021 23:38:53
User entered '23 Oct 2020 UN:UN' (non-conformant).	System	07 Apr 2021 23:38:32
User entered empty.	System	23 Oct 2020 22:28:21

US3432517

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:03

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:29:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered 'Grade 1/Mild (Grade 1/Mild)'	Phoebe Cunningham (b) (4)	23 Oct 2020 22:28:21

US3432517

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:29:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered 'No (N)'	Phoebe Cunningham (b) (4)	23 Oct 2020 22:28:21

US3432517

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:03

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:29:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered '0'	Phoebe Cunningham (b) (4)	23 Oct 2020 22:28:21

US3432517

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:03

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:29:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered '0'	Phoebe Cunningham (b) (4)	23 Oct 2020 22:28:21

US3432517

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:29:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered '0'	Phoebe Cunningham (b) (4)	23 Oct 2020 22:28:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:29:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered empty.	Phoebe Cunningham (b) (4)	23 Oct 2020 22:28:21

US3432517

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:03

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:29:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered empty.	Phoebe Cunningham (b) (4)	23 Oct 2020 22:28:21

US3432517

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:29:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered empty.	Phoebe Cunningham (b) (4)	23 Oct 2020 22:28:21

US3432517

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 20:29:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered empty.	Phoebe Cunningham (b) (4)	23 Oct 2020 22:28:21

US3432517

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:29:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered '0'	Phoebe Cunningham (b) (4)	23 Oct 2020 22:28:21

US3432517

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:29:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered '0'	Phoebe Cunningham (b) (4)	23 Oct 2020 22:28:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:03

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:29:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered '0'	Phoebe Cunningham (b) (4)	23 Oct 2020 22:28:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:29:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered 'Related (RELATED)'	Phoebe Cunningham (b) (4)	23 Oct 2020 22:28:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:29:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered 'Not Related (NOT RELATED)'	Phoebe Cunningham (b) (4)	23 Oct 2020 22:28:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:03

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:29:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered 'None (NONE)'	Phoebe Cunningham (b) (4)	23 Oct 2020 22:28:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:03

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:29:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered 'I'	Phoebe Cunningham (b) (4)	23 Oct 2020 22:28:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:29:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered '0'	Phoebe Cunningham (b) (4)	23 Oct 2020 22:28:21

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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 20:29:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered '0'	Phoebe Cunningham (b) (4)	23 Oct 2020 22:28:21

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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 20:29:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Phoebe Cunningham (b) (4)	23 Oct 2020 22:28:21

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:03

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 20:29:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered empty.	Phoebe Cunningham (b) (4)	23 Oct 2020 22:28:21

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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 20:29:05
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
User entered empty.	Phoebe Cunningham (b) (4)	23 Oct 2020 22:28:21

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Folder: Adverse Events

Form: Adverse Events (2)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:29:05
User entered '0'	System	23 Oct 2020 22:28:21

US3432517

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:03

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:29:05
User entered '0'	System	23 Oct 2020 22:28:21

US3432517

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:40:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 20:29:05

US3432517

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:03

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:02:37
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:40
User entered	System	10 Feb 2021 15:13:35
'USA-US078-2021-mRNA-1273-P301000016'		
User entered 'New'	(b) (4), (b) (6)	10 Feb 2021 15:13:35

US3432517

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:03

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:02:37
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Kidney stones - version MedDRA\\23.0.	Coder Import (b) (4)	09 Feb 2021 21:52:37
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Feb 2021 21:52:37
	(b) (4)	
Data point term sent to Coder	System	09 Feb 2021 21:51:58
User entered 'Kidney Stones'	Monica Feeley (b) (4)	09 Feb 2021 21:51:17
	(b) (4)	

US3432517

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:02:37
User entered 'Yes (Y)'	Monica Feeley (b) (4)	09 Feb 2021 21:51:17
	(b) (4)	

US3432517

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:24:43
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	03 Mar 2021 15:02:37
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	09 Feb 2021 21:51:17

US3432517

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:02:37
User entered 'No (N)'	Monica Feeley (b) (4)	09 Feb 2021 21:51:17
	(b) (4)	

US3432517

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:02:37
User entered '02 Feb 2021'	Monica Feeley (b) (4)	09 Feb 2021 21:51:17
	(b) (4)	

US3432517

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:03

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:02:37
User entered empty.	Monica Feeley (b) (4)	09 Feb 2021 21:51:17
	(b) (4)	

US3432517

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 21:51:17

US3432517

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:02:37
User entered 'No (N)'	Monica Feeley (b) (4)	09 Feb 2021 21:51:17
	(b) (4)	

US3432517

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:02:37
User entered '3 Feb 2021'	Monica Feeley (b) (4)	09 Feb 2021 21:51:17
	(b) (4)	

US3432517

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:03

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:02:37
User entered empty.	Monica Feeley (b) (4)	09 Feb 2021 21:51:17
	(b) (4)	

US3432517

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 21:51:17

US3432517

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:03

Severity

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:02:37
	(b) (4), (b) (6)	
User closed query 'PV Query: Since the subject was hospitalized for the event of Kidney stones, appropriate CTCAE grade should be grade 3 instead of grade 1/grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain. ' (Site from Safety).		02 Mar 2021 18:00:51
Query 'PV Query: Since the subject was hospitalized for the event of Kidney stones, appropriate CTCAE grade should be grade 3 instead of grade 1/grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain. ' answered with 'updated' (Site from Safety).	Monica Feeley (b) (4)	01 Mar 2021 22:46:57
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	(b) (4)	01 Mar 2021 22:46:30
User opened query 'PV Query: Since the subject was hospitalized for the event of Kidney stones, appropriate CTCAE grade should be grade 3 instead of grade 1/grade 2. Please update the event severity as such. If the severity is to remain grade 2, please clarify/explain. ' (Site from Safety).	(b) (4), (b) (6)	17 Feb 2021 14:06:05
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Monica Feeley (b) (4)	09 Feb 2021 21:51:17
	(b) (4)	

US3432517

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:02:37
User entered 'Yes (Y)'	Monica Feeley (b) (4)	09 Feb 2021 21:51:17
	(b) (4)	

US3432517

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:02:37
User entered '0'	Monica Feeley (b) (4)	09 Feb 2021 21:51:17
	(b) (4)	

US3432517

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:02:37
User entered '0'	Monica Feeley (b) (4)	09 Feb 2021 21:51:17
	(b) (4)	

US3432517

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:02:37
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 18:00:57
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'sent discharge summary' (Site from Safety).	Monica Feeley (b) (4)	01 Mar 2021 23:17:26
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	17 Feb 2021 14:06:23
User entered 'I'	Monica Feeley (b) (4)	09 Feb 2021 21:51:17

US3432517

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:03

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:02:37
User entered '2 Feb 2021'	Monica Feeley (b) (4)	09 Feb 2021 21:51:17
	(b) (4)	

US3432517

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:03

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:02:37
User entered '3 Feb 2021'	Monica Feeley (b) (4)	09 Feb 2021 21:51:17
	(b) (4)	

US3432517

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:02:37
User entered 'No (N)'	Monica Feeley (b) (4)	09 Feb 2021 21:51:17
	(b) (4)	

US3432517

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 11:24:43
DataPoint Verified.	(b) (4), (b) (6) [REDACTED]	03 Mar 2021 15:02:37
User entered empty.	Monica Feeley (b) (4) (b) (4)	09 Feb 2021 21:51:17

US3432517

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:02:37
User entered '0'	Monica Feeley (b) (4)	09 Feb 2021 21:51:17
	(b) (4)	

US3432517

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:02:37
User entered '0'	Monica Feeley (b) (4)	09 Feb 2021 21:51:17
	(b) (4)	

US3432517

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:02:37
User entered '0'	Monica Feeley (b) (4)	09 Feb 2021 21:51:17
	(b) (4)	

US3432517

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:02:37
User entered 'Not Related (NOT RELATED)'	Monica Feeley (b) (4)	09 Feb 2021 21:51:17
	(b) (4)	

US3432517

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:02:37
User entered 'Not Related (NOT RELATED)'	Monica Feeley (b) (4)	09 Feb 2021 21:51:17
	(b) (4)	

US3432517

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:03

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
	(b) (4), (b) (6)	03 Mar 2021 15:02:37
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 18:01:04
User closed query 'PV Query: As the subject received both doses prior to the onset of the event, please consider updating the action taken to not applicable. ' (Site from Safety).	Monica Feeley (b) (4)	01 Mar 2021 22:48:05
Query 'PV Query: As the subject received both doses prior to the onset of the event, please consider updating the action taken to not applicable. ' answered with 'updated' (Site from Safety).	Monica Feeley (b) (4)	01 Mar 2021 22:47:15
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Feb 2021 14:06:37
User opened query 'PV Query: As the subject received both doses prior to the onset of the event, please consider updating the action taken to not applicable. ' (Site from Safety).	Monica Feeley (b) (4)	09 Feb 2021 21:51:17
User entered 'None (NONE)'	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:03

None

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:02:37
User entered '0'	Monica Feeley (b) (4)	09 Feb 2021 21:51:17
	(b) (4)	

US3432517

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:02:37
	(b) (4), (b) (6)	
User closed query 'Per DM: ConMed is checked on AE of KIDNEY STONES; however, there is no matching indication given on Con Med eCRF. Please review and update as appropriate. ' (Site from DM). Query 'Per DM: ConMed is checked on AE of KIDNEY STONES; however, there is no matching indication given on Con Med eCRF. Please review and update as appropriate. ' answered with 'updated con meds' (Site from DM).	Monica Feeley (b) (4)	01 Mar 2021 22:48:11
	(b) (4)	
User opened query 'Per DM: ConMed is checked on AE of KIDNEY STONES; however, there is no matching indication given on Con Med eCRF. Please review and update as appropriate. ' (Site from DM). User entered 'I'	(b) (4), (b) (6)	24 Feb 2021 16:54:14
	(b) (4), (b) (6)	
	Monica Feeley (b) (4)	09 Feb 2021 21:51:17
	(b) (4)	

US3432517

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	Jessica Cauley (b) (4)	04 Apr 2021 10:48:03
Query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.'	(b) (4)	29 Mar 2021 19:22:28
answered with 'please see CT of abdomen/pelvis in con procedures.' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 01:49:45
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	03 Mar 2021 15:02:37
DataPoint Verified.	(b) (4)	01 Mar 2021 22:56:01
User entered '1' reason for change: New Information	Monica Feeley (b) (4)	09 Feb 2021 21:51:17
User entered '0'	(b) (4)	

US3432517

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:03

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:02:37
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Monica Feeley (b) (4)	09 Feb 2021 21:51:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:03

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
	(b) (4), (b) (6)	03 Mar 2021 15:02:37
DataPoint Verified.	Monica Feeley (b) (4)	09 Feb 2021 21:51:17
User entered empty.	(b) (4)	

US3432517

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:03

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 11:24:43
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:21:31
User closed query 'PV Query: If available, please provide date and results of subject outpatient follow-up.' (Site from Safety).	(b) (4), (b) (6)	12 Mar 2021 19:21:01
Query 'PV Query: If available, please provide date and results of subject outpatient follow-up.' answered with 'we have updated narrative with this:	Monica Feeley (b) (4)	11 Mar 2021 16:56:41
17FEB2021- follow up. pain resolved but stone not passed.	(b) (4)	
01MAR2021- follow up. pain resolved and stone passed.' (Site from Safety).		
DataPoint Un-verified.	Monica Feeley (b) (4)	11 Mar 2021 16:56:26
User entered 'PATIENT HOSPITALIZED OVERNIGHT 2FEB21-3FEB21 FOR KIDNEY STONES. GIVEN 600 MG OF IBUPROFEN PRN AND FLOMAX QD 1 PILL. PARTICIPANT KEPT IN ED OVERNIGHT FOR MONITORING.	(b) (4)	
	Monica Feeley (b) (4)	11 Mar 2021 16:56:26
	(b) (4)	
CT OF ABDOMEN/PELVIS PERFORMED		
02FEB2021- SHOWED A 4 MM STONE WITHIN THE DISTAL LEFT URETER		
17FEB2021- follow up. pain resolved but stone not passed.		
01MAR2021- follow up. pain resolved and stone passed.' reason for change: New Information		
User opened query 'PV Query: If available, please provide date and results of subject outpatient follow-up.' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 21:26:48
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:02:37

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:03

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 18:00:36
User closed query 'Per DM CLR: Narrative = GIVEN 600 MG OF IBUPROFEN PRN AND FLOMAX QD 1 PILL. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 04:17:59
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' answered with 'please see updates to narrative' (Site from Safety).	Monica Feeley (b) (4)	01 Mar 2021 23:11:07
User entered 'PATIENT HOSPITALIZED OVERNIGHT 2FEB21-3FEB21 FOR KIDNEY STONES. GIVEN 600 MG OF IBUPROFEN PRN AND FLOMAX QD 1 PILL. PARTICIPANT KEPT IN ED OVERNIGHT FOR MONITORING.	Monica Feeley (b) (4)	01 Mar 2021 23:10:54
CT of abdomen/pelvis performed 02FEB2021- showed a 4 mm stone within the distal left ureter' reason for change: New Information		
Query 'Per DM CLR: Narrative = GIVEN 600 MG OF IBUPROFEN PRN AND FLOMAX QD 1 PILL. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated con meds' (Site from DM).	Monica Feeley (b) (4)	01 Mar 2021 22:48:17

US3432517

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:03

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative = GIVEN 600 MG OF IBUPROFEN PRN AND FLOMAX QD 1 PILL. However, this is not recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 09:36:01
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. ' (Site from Safety).	(b) (4), (b) (6)	17 Feb 2021 14:05:43
User entered 'Patient hospitalized overnight 2FEB21-3FEB21 for kidney stones. Given 600 mg of ibuprofen PRN and flomax qd 1 pill. Participant kept in ED overnight for monitoring.'	Monica Feeley (b) (4)	09 Feb 2021 21:51:17

US3432517

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:03

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Feb 2021 21:51:17

US3432517

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:03

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Feb 2021 21:51:17

US3432517

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:40:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Feb 2021 21:51:17

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:40:03

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:58:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	Megan Powell (b) (4)	17 Sep 2020 18:25:54

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 16:02:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 16:02:40
Data point term sent to Coder	System	07 Dec 2020 19:08:40
Data point term sent to Coder	System	07 Dec 2020 19:06:33
Coding entries removed.	Kathleen Garvey (b) (4) (b) (4)	07 Dec 2020 19:06:20
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 18:28:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Sep 2020 18:28:37
Data point term sent to Coder	System	17 Sep 2020 18:27:39
User entered 'Naproxen'	Megan Powell (b) (4) (b) (4)	17 Sep 2020 18:26:59

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'No (N)'	Megan Powell (b) (4)	17 Sep 2020 18:26:59
	(b) (4)	

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User closed query 'Per DM CLR-RQ: Response noted. Review if Body Aches should be recorded as MH. Else, if used as prophylaxis, please update this field to reflect this and update "prophylaxis" field above. Else, provide further clarification. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 15:34:10
Query 'Per DM CLR-RQ: Response noted. Review if Body Aches should be recorded as MH. Else, if used as prophylaxis, please update this field to reflect this and update "prophylaxis" field above. Else, provide further clarification. ' answered with 'pt is a runner, uses medication as needed after runs' (Site from DM).	Kathleen Garvey (b) (4)	07 Dec 2020 19:07:46
User entered 'GENERALIZED BODY ACHES/SORENESS after running' reason for change: New Information	Kathleen Garvey (b) (4)	07 Dec 2020 19:07:41
User entered 'generalized BODY ACHES/soreness' reason for change: New Information	Kathleen Garvey (b) (4)	07 Dec 2020 19:06:20
User opened query 'Per DM CLR-RQ: Response noted. Review if Body Aches should be recorded as MH. Else, if used as prophylaxis, please update this field to reflect this and update "prophylaxis" field above. Else, provide further clarification. ' (Site from DM).	(b) (4), (b) (6)	29 Nov 2020 03:27:28
User closed query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Nov 2020 03:27:28
Query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' answered with 'pt is a regular long distance runner, reports he often runs over 40 miles a week and takes medication PRN for aches and soreness' (Site from DM).	Kathleen Garvey (b) (4)	05 Nov 2020 18:18:11

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:03

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 10:58:31
User entered 'Body aches'	Megan Powell (b) (4)	17 Sep 2020 18:26:59

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '500'	Megan Powell (b) (4)	17 Sep 2020 18:26:59
	(b) (4)	

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'mg (mg)'	Megan Powell (b) (4)	17 Sep 2020 18:26:59
	(b) (4)	

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 03:10:38
User entered empty.	Megan Powell (b) (4) (b) (4)	17 Sep 2020 18:26:59

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'as needed (PRN)'	Megan Powell (b) (4)	17 Sep 2020 18:26:59
	(b) (4)	

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 03:10:38
User entered empty.	Megan Powell (b) (4) (b) (4)	17 Sep 2020 18:26:59

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Oral (ORAL)'	Megan Powell (b) (4)	17 Sep 2020 18:26:59
	(b) (4)	

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered empty.	Megan Powell (b) (4)	17 Sep 2020 18:26:59
	(b) (4)	

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:03

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'UN UNK 2010'	Megan Powell (b) (4)	17 Sep 2020 18:26:59
	(b) (4)	

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '0'	Megan Powell (b) (4)	17 Sep 2020 18:26:59
	(b) (4)	

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	Megan Powell (b) (4) (b) (4)	17 Sep 2020 18:26:59

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 03:10:38
User entered empty.	Megan Powell (b) (4) (b) (4)	17 Sep 2020 18:26:59

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'No (N)'	Megan Powell (b) (4)	17 Sep 2020 18:26:59
	(b) (4)	

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 18:26:59

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 18:26:59

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:40:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 18:26:59

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: ANTACIDS, ATC: CALCIUM COMPOUNDS, PRODUCT: CALCIUM CARBONATE, PRODUCTSYNONYM: TUMS [CALCIUM CARBONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 18:30:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 18:30:41
Data point term sent to Coder	System	17 Sep 2020 18:29:42
User entered 'TUMS'	Megan Powell (b) (4)	17 Sep 2020 18:29:04
	(b) (4)	

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 03:10:38
User entered 'No (N)'	Megan Powell (b) (4) (b) (4)	17 Sep 2020 18:29:04

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 03:10:38
User entered 'GERD'	Megan Powell (b) (4) (b) (4)	17 Sep 2020 18:29:04

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'UNK' reason for change: Data Entry Error	Megan Powell (b) (4)	17 Sep 2020 18:44:25
User entered '500'	Megan Powell (b) (4)	17 Sep 2020 18:29:04

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'tablet (TABLET)' reason for change:	Megan Powell (b) (4)	17 Sep 2020 18:44:25
Data Entry Error	(b) (4)	
User entered 'mg (mg)'	Megan Powell (b) (4)	17 Sep 2020 18:29:04
	(b) (4)	

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 03:10:38
User entered empty.	Megan Powell (b) (4) (b) (4)	17 Sep 2020 18:29:04

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'as needed (PRN)'	Megan Powell (b) (4)	17 Sep 2020 18:29:04
	(b) (4)	

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 03:10:38
User entered empty.	Megan Powell (b) (4) (b) (4)	17 Sep 2020 18:29:04

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 03:10:38
User entered 'Oral (ORAL)'	Megan Powell (b) (4) (b) (4)	17 Sep 2020 18:29:04

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered empty.	Megan Powell (b) (4)	17 Sep 2020 18:29:04
	(b) (4)	

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'UN UNK 2015'	Megan Powell (b) (4)	17 Sep 2020 18:29:04
	(b) (4)	

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:03

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '0'	Megan Powell (b) (4)	17 Sep 2020 18:29:04
	(b) (4)	

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	Megan Powell (b) (4)	17 Sep 2020 18:29:04
	(b) (4)	

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 03:10:38
User entered empty.	Megan Powell (b) (4) (b) (4)	17 Sep 2020 18:29:04

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'No (N)'	Megan Powell (b) (4)	17 Sep 2020 18:29:04
	(b) (4)	

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 18:29:04

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 18:29:04

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:40:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 18:29:04

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:46:28
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:12:14
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Mar 2021 22:58:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	01 Mar 2021 22:58:56
Data point term sent to Coder	System	01 Mar 2021 22:58:00
User entered 'Ibuprofen'	Monica Feeley (b) (4)	01 Mar 2021 22:57:35

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:46:28
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:12:14
User entered 'No (N)'	Monica Feeley (b) (4)	01 Mar 2021 22:57:35

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:46:28
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:12:14
User entered 'Kidney Stones'	Monica Feeley (b) (4)	01 Mar 2021 22:57:35

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:46:28
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:12:14
User entered '600'	Monica Feeley (b) (4)	01 Mar 2021 22:57:35

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:46:28
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:12:14
User entered 'mg (mg)'	Monica Feeley (b) (4)	01 Mar 2021 22:57:35

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:46:28
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:12:14
User entered empty.	Monica Feeley (b) (4)	01 Mar 2021 22:57:35

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:46:28
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:12:14
User entered 'other (OTHER)'	Monica Feeley (b) (4)	01 Mar 2021 22:57:35

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:46:28
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:12:14
User entered 'every 6 hr PRN'	Monica Feeley (b) (4)	01 Mar 2021 22:57:35

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:46:28
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:12:14
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	01 Mar 2021 22:57:35

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:46:28
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:12:14
User entered empty.	Monica Feeley (b) (4)	01 Mar 2021 22:57:35

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:46:28
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:12:14
User entered '03 Feb 2021'	Monica Feeley (b) (4)	01 Mar 2021 22:57:35

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:46:28
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:12:14
User entered '0'	Monica Feeley (b) (4)	01 Mar 2021 22:57:35

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:46:28
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 10:20:37
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'upadted' (Site from DM).	Jessica Cauley (b) (4)	17 Mar 2021 13:23:47
DataPoint Un-verified.	Bethany Evans (b) (4)	15 Mar 2021 19:15:17
User entered 'No (N)' reason for change: New Information	Bethany Evans (b) (4)	15 Mar 2021 19:15:17
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 06:34:23
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:12:14
User entered 'Yes (Y)'	Monica Feeley (b) (4)	01 Mar 2021 22:57:35

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:46:28
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
DataPoint Un-verified.	Bethany Evans (b) (4)	15 Mar 2021 19:15:17
User entered '07 Feb 2021' reason for change: New Information	Bethany Evans (b) (4)	15 Mar 2021 19:15:17
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:12:14
User entered empty.	Monica Feeley (b) (4)	01 Mar 2021 22:57:35

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:46:28
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:12:14
User entered 'No (N)'	Monica Feeley (b) (4)	01 Mar 2021 22:57:35

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:46:28
User entered empty.	System	01 Mar 2021 22:57:35

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:46:28
User entered empty.	System	01 Mar 2021 22:57:35

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:40:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:46:28
User entered empty.	System	01 Mar 2021 22:57:35

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:46:39
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:12:38
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN HYDROCHLORIDE, PRODUCTSYNONYM: FLOMAX [TAMSULOSIN HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Mar 2021 22:59:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Mar 2021 22:59:58
Data point term sent to Coder	System	01 Mar 2021 22:59:05
User entered 'Flomax'	Monica Feeley (b) (4)	01 Mar 2021 22:58:10

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:46:39
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:12:38
User entered 'No (N)'	Monica Feeley (b) (4)	01 Mar 2021 22:58:10

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:46:39
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:12:38
User entered 'Kidney Stones'	Monica Feeley (b) (4)	01 Mar 2021 22:58:10

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:46:39
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:12:38
User entered '0.4'	Monica Feeley (b) (4)	01 Mar 2021 22:58:10

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:46:39
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:12:38
User entered 'mg (mg)'	Monica Feeley (b) (4)	01 Mar 2021 22:58:10

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:46:39
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:12:38
User entered empty.	Monica Feeley (b) (4)	01 Mar 2021 22:58:10

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:46:39
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:12:38
User entered 'once daily (QD)'	Monica Feeley (b) (4)	01 Mar 2021 22:58:10

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:46:39
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:12:38
User entered empty.	Monica Feeley (b) (4)	01 Mar 2021 22:58:10

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:46:39
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:12:38
User entered 'Oral (ORAL)'	Monica Feeley (b) (4)	01 Mar 2021 22:58:10

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:46:39
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:12:38
User entered empty.	Monica Feeley (b) (4)	01 Mar 2021 22:58:10

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:46:39
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:12:38
User entered '03 Feb 2021'	Monica Feeley (b) (4)	01 Mar 2021 22:58:10

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:46:39
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:12:38
User entered '0'	Monica Feeley (b) (4)	01 Mar 2021 22:58:10

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:46:39
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:12:38
User entered 'No (N)'	Monica Feeley (b) (4)	01 Mar 2021 22:58:10

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:46:39
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:12:38
User entered '10 Feb 2021'	Monica Feeley (b) (4)	01 Mar 2021 22:58:10

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:46:39
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:12:38
User entered 'No (N)'	Monica Feeley (b) (4)	01 Mar 2021 22:58:10

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:46:39
User entered '1'	System	01 Mar 2021 22:58:10

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:46:39
User entered '1'	System	01 Mar 2021 22:58:10

US3432517

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:40:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:46:39
User entered '804 (804)'	System	01 Mar 2021 22:58:10

US3432517

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:40:03

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 04:58:20
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Nov 2020 16:19:55

US3432517

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:40:03

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '03 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 16:20:34

US3432517

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:40:03

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	19 Feb 2021 03:10:38
User entered 'Colonoscopy'	(b) (4), (b) (6) [REDACTED]	12 Nov 2020 16:20:34

US3432517

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:40:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'Diagnostic (DIAGNOSTIC)'	(b) (4), (b) (6)	12 Nov 2020 16:20:34

US3432517

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:40:03

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 16:20:34

US3432517

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:40:03

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:12:50
User entered '02 Feb 2021'	Monica Feeley (b) (4)	01 Mar 2021 22:56:43

US3432517

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:40:03

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:12:50
User entered 'CT of abdomen/pelvis'	Monica Feeley (b) (4)	01 Mar 2021 22:56:43

US3432517

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:40:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:12:50
User entered 'Adverse Event (AE)'	Monica Feeley (b) (4)	01 Mar 2021 22:56:43

US3432517

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:40:03

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:33:17
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:12:50
User entered empty.	Monica Feeley (b) (4)	01 Mar 2021 22:56:43

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'USA-US078-2021-MRNA-1273-P301000016'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'Yes (Y)'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'No (N)'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'No (N)'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'Yes (Y)'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'No (N)'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'No (N)'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'No (N)'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'Lindsey'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'Baden'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'MA'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 18:01:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'US'	System	10 Feb 2021 15:13:58

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	12 Mar 2021 19:20:27
User entered '2'	System	02 Mar 2021 18:01:31
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '1'	System	10 Feb 2021 15:13:58

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'USA-US078-2021-MRNA-1273-P301000016'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'Yes (Y)'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'No (N)'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'No (N)'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'Yes (Y)'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'No (N)'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'No (N)'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'No (N)'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'Lindsey'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'Baden'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'MA'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 18:01:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'US'	System	10 Feb 2021 15:13:58

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	12 Mar 2021 19:20:27
User entered '2'	System	02 Mar 2021 18:01:31
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '1'	System	10 Feb 2021 15:13:58

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:40:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '10/Feb/2021 10:13'	System	10 Feb 2021 15:13:58

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:40:03

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 18:01:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'I'	(b) (4), (b) (6)	10 Feb 2021 15:13:58

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'USA-US078-2021-MRNA-1273-P301000016'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'Yes (Y)'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'No (N)'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'No (N)'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'Yes (Y)'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'No (N)'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'No (N)'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'No (N)'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'Lindsey'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'Baden'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'MA'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 18:01:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'US'	System	10 Feb 2021 15:13:58

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	12 Mar 2021 19:20:27
User entered '2'	System	02 Mar 2021 18:01:31
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '1'	System	10 Feb 2021 15:13:58

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:40:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User entered '02/Mar/2021 13:01'	System	02 Mar 2021 18:01:31

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:40:03

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
Reviewed for Safety.	(b) (4), (b) (6)	12 Mar 2021 19:19:49
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User entered 'I'	(b) (4), (b) (6)	02 Mar 2021 18:01:31

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'USA-US078-2021-MRNA-1273-P301000016'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'Yes (Y)'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'No (N)'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'No (N)'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'Yes (Y)'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'No (N)'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'No (N)'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'No (N)'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'Lindsey'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'Baden'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
Reviewed for Safety.	(b) (4), (b) (6)	10 Feb 2021 15:13:51
User entered 'MA'	System	10 Feb 2021 15:13:35

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 Mar 2021 15:06:15
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 18:01:18
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered 'US'	System	10 Feb 2021 15:13:58

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form

Generated On: 09 Jun 2021 17:40:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	12 Mar 2021 19:20:27
User entered '2'	System	02 Mar 2021 18:01:31
User signature succeeded.	Lindsey Baden (b) (4)	19 Feb 2021 03:10:38
User entered '1'	System	10 Feb 2021 15:13:58

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:40:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:21:45
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered '12/Mar/2021 14:20'	System	12 Mar 2021 19:20:27

US3432517

Folder: SAE USA-US078-2021-MRNA-1273-P301000016

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:40:03

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 03:21:45
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 21:07:54
User entered 'I'	(b) (4), (b) (6)	12 Mar 2021 19:20:27