

US3432081 (Prod: Brigham and Womens Hospital)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:31:17

All time stamps listed in this document are displayed in GMT

US3432081

Form: Participant Creation

Data signed: (b) (4) 16 Feb 2021 00:03:27

Generated On: 09 Jun 2021 17:31:17

Participant ID

US3432081

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

US3432081

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

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

Visit date (dd MMM yyyy)	10 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3432081

Folder: Screening

Form: Demographics

Data signed: (b) (4) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

Date of Birth (MMM yyyy)	(b) (6) 1991
Age	28
Age Units	YEARS
Age (Derived)	28
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	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) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

Date of Informed Consent (*dd MMM yyyy*) 10 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input checked="" type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input type="radio"/>
Amendment 4	<input type="radio"/>
Amendment 5	<input type="radio"/>

Was participant enrolled in the study?

Yes	<input checked="" type="radio"/>
No	<input type="radio"/>

If No, indicate reason for screen fail

Withdrew Consent	<input type="radio"/>
Inclusion/Exclusion	<input type="radio"/>
Cohort Full	<input type="radio"/>
Other	<input type="radio"/>

If reason for screen fail is Other, specify _____

Was this participant screened previously?

Yes	<input type="radio"/>
No	<input checked="" type="radio"/>

If Yes, previous participant number _____

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 16 Feb 2021 00:03:28

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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) 16 Feb 2021 00:03:28

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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) 16 Feb 2021 00:03:28

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Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 00:03:28

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	10 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	16:00 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 16:00
Height (<i>xxx.x</i>)	161 cm
Weight (<i>xxx.x</i>)	55.9 kg
BMI (<i>xxx.x</i>)	21.56553 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 00:03:28

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

Date of assessment (dd MMM yyyy) 10 AUG 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

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

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 16 Feb 2021 00:03:28

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Was the pregnancy test performed? Yes ☒
No ☐

Date of test (dd MMM yyyy) 10 AUG 2020

Test performed Urine ☒
Serum ☐

Result Positive ☐
Negative ☒

Was FSH sample collected? Yes ☐
No ☒

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 16 Feb 2021 00:03:28

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 16 Feb 2021 00:03:28

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	True
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

What was the date of randomization? (dd MMM yyyy) 10 AUG 2020

What was the participant's randomization number? 102732

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

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) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

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)	10 AUG 2020
Time of assessment (00:00-23:59)	16:00 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 16:00
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	54 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 AUG 2020
Time of assessment (00:00-23:59)	17:08 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 17:08
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)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☒

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

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) 10 AUG 2020

What was the treatment time? (00:00-23:59) 16:37 (24 HR)

Treatment Date and Time (derived) 10 AUG 2020 16:37

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) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 10 AUG 2020

Collection time (00:00-23:59) 16:15 (24 HR)

Collection date and time (derived) 10 AUG 2020 16:15

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

Collection date (dd MMM yyyy)			10 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:20	10 AUG 2020 16:20
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

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 17:31:17

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

10 AUG 2020 17:11

PC Open Date & Time

10 AUG 2020 16:57

PC Close Date & Time

10 AUG 2020 19:27

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

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 96.5 °F

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

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

PC Time Stamp	10 AUG 2020 20:33
PC Open Date & Time	10 AUG 2020 20:22
PC Close Date & Time	11 AUG 2020 11:59

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:17

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

96.2 °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

11 AUG 2020 13:01

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:17

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

94.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 15:08

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:17

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

96.8 °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

13 AUG 2020 16:35

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:17

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

96.0 °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

14 AUG 2020 15:01

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:17

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

96.0 °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 AUG 2020 15:24

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:17

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

95.6 °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

16 AUG 2020 17:30

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 17:12

PC Open Date & Time

10 AUG 2020 16:57

PC Close Date & Time

10 AUG 2020 19:27

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

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

10 AUG 2020 20:34

PC Open Date & Time

10 AUG 2020 20:22

PC Close Date & Time

11 AUG 2020 11:59

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:17

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

11 AUG 2020 13:01

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:17

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

12 AUG 2020 15:06

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:17

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

13 AUG 2020 16:34

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:17

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

14 AUG 2020 15:14

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:17

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

15 AUG 2020 15:24

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:17

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

16 AUG 2020 17:30

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

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 ☐

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 17:12
PC Open Date & Time	10 AUG 2020 16:57
PC Close Date & Time	10 AUG 2020 19:27

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

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 ☐

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 20:34
PC Open Date & Time	10 AUG 2020 20:22
PC Close Date & Time	11 AUG 2020 11:59

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:17

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 ☒

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:17

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 13:01
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:17

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 ☒

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:17

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 15:07
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:17

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)

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:17

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 16:35
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:17

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

51 of 1771

EAB) (1725)

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:17

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 15:18
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:17

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

53 of 1771

EAB) (1725)

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:17

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 15:25
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:17

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 ☒

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:17

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 17:30
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3432081

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 17 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3432081

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432081

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3432081

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432081

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 31 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3432081

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432081

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 00:03:29

Generated On: 09 Jun 2021 17:31:17

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3432081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 00:03:29

Generated On: 09 Jun 2021 17:31:17

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 SEP 2020
Time of assessment (00:00-23:59)	16:17 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 16:17
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	062 mmHg
Diastolic Blood Pressure units	MMHG

US3432081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 00:03:29

Generated On: 09 Jun 2021 17:31:17

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)	8 SEP 2020
Time of assessment (00:00-23:59)	18:29 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 18:29
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3432081

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 00:03:29

Generated On: 09 Jun 2021 17:31:17

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 SEP 2020

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

US3432081

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 16 Feb 2021 00:03:29

Generated On: 09 Jun 2021 17:31:17

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	8 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3432081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 00:03:29

Generated On: 09 Jun 2021 17:31:17

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) 8 SEP 2020

What was the treatment time? (00:00-23:59) 17:59 (24 HR)

Treatment Date and Time (derived) 8 SEP 2020 17:59

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

US3432081

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 00:03:29

Generated On: 09 Jun 2021 17:31:17

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

Collection date (dd MMM yyyy)	8 SEP 2020
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Collection time (00:00-23:59)	16:55 (24 HR)
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Collection date and time (derived)	8 SEP 2020 16:55
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US3432081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 00:03:29

Generated On: 09 Jun 2021 17:31:17

Collection date (dd MMM yyyy)			8 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:05	8 SEP 2020 17:05
Nasopharyngeal Swab 2	No		

US3432081

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 00:03:29

Generated On: 09 Jun 2021 17:31:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

08 SEP 2020 18:31

PC Open Date & Time

08 SEP 2020 18:19

PC Close Date & Time

08 SEP 2020 20:49

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

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	08 SEP 2020 21:44
PC Open Date & Time	08 SEP 2020 21:44
PC Close Date & Time	09 SEP 2020 11:59

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:17

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

96.8 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

09 SEP 2020 12:06

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:17

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

96.6 °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

10 SEP 2020 15:38

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:17

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 ☒

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

Yes ☐

No ☒

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

PC Time Stamp 11 SEP 2020 14:41

PC Open Date & Time 11 SEP 2020 12:00

PC Close Date & Time 12 SEP 2020 11:59

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:17

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

95.1 °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

12 SEP 2020 16:57

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:17

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

96.1 °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

13 SEP 2020 19:02

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:17

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

95.7 °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

14 SEP 2020 21:36

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

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

08 SEP 2020 18:31

PC Open Date & Time

08 SEP 2020 18:19

PC Close Date & Time

08 SEP 2020 20:49

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

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

08 SEP 2020 21:44

PC Open Date & Time

08 SEP 2020 21:44

PC Close Date & Time

09 SEP 2020 11:59

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:17

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

09 SEP 2020 12:06

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:17

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

10 SEP 2020 15:38

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:17

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

11 SEP 2020 14:42

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:17

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

12 SEP 2020 16:57

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:17

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

13 SEP 2020 19:03

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:17

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

14 SEP 2020 21:35

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

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 ☐

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 18:32
PC Open Date & Time	08 SEP 2020 18:19
PC Close Date & Time	08 SEP 2020 20:49

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

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 ☐

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 21:44
PC Open Date & Time	08 SEP 2020 21:44
PC Close Date & Time	09 SEP 2020 11:59

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:17

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 ☒

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:17

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 12:05
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:17

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 ☒

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:17

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 15:38
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:17

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 ☒

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:17

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 14:42
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:17

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 ☒

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:17

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 16:57
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:17

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 ☒

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:17

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 19:03
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:17

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 ☒

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US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:17

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 21:35
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3432081

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3432081

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432081

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3432081

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432081

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3432081

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432081

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 00:03:29

Generated On: 09 Jun 2021 17:31:17

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3432081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 00:03:29

Generated On: 09 Jun 2021 17:31:17

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	14:29 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 14:29
Temperature (xxx.x)	036.4 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	052 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	014 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	075 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432081

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 00:03:29

Generated On: 09 Jun 2021 17:31:17

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 OCT 2020

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

US3432081

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 00:03:29

Generated On: 09 Jun 2021 17:31:17

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

Collection date (dd MMM yyyy)	13 OCT 2020
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Collection time (00:00-23:59)	14:49 (24 HR)
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Collection date and time (derived)	13 OCT 2020 14:49
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US3432081

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 00:03:29

Generated On: 09 Jun 2021 17:31:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

10 OCT 2020 11:28:07

Patient Cloud Open Date & Time

10 OCT 2020 00:01

Patient Cloud Close Date & Time

14 OCT 2020 23:59

US3432081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 OCT 2020 10:36:18

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3432081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 OCT 2020 09:09:43
Patient Cloud Open Date & Time	24 OCT 2020 00:01
Patient Cloud Close Date & Time	28 OCT 2020 23:59

US3432081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 NOV 2020 09:58:47
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3432081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 NOV 2020 08:59:42
Patient Cloud Open Date & Time	14 NOV 2020 00:01
Patient Cloud Close Date & Time	18 NOV 2020 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

21 NOV 2020 00:14:57

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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	25 NOV 2020 09:24:36
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

02 DEC 2020 11:08:12

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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	09 DEC 2020 10:10:43
Patient Cloud Open Date & Time	09 DEC 2020 00:01
Patient Cloud Close Date & Time	13 DEC 2020 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

16 DEC 2020 09:24:47

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

23 DEC 2020 09:19:06

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 DEC 2020 07:35:51

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

06 JAN 2021 00:19:00

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 JAN 2021 00:01
Patient Cloud Close Date & Time	17 JAN 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	23 JAN 2021 09:23:08
Patient Cloud Open Date & Time	20 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

27 JAN 2021 07:00:44

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 FEB 2021 06:27:54
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

10 FEB 2021 09:25:44

Patient Cloud Open Date & Time

10 FEB 2021 00:01

Patient Cloud Close Date & Time

14 FEB 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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	17 FEB 2021 09:55:14
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

24 FEB 2021 10:24:20

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

03 MAR 2021 10:06:07

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

10 MAR 2021 14:15:33

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 MAR 2021 10:30:50
Patient Cloud Open Date & Time	17 MAR 2021 00:01
Patient Cloud Close Date & Time	21 MAR 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

24 MAR 2021 10:45:39

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 MAR 2021 06:29:13

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 APR 2021 13:33:52
Patient Cloud Open Date & Time	07 APR 2021 00:01
Patient Cloud Close Date & Time	11 APR 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 APR 2021 07:08:43

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 APR 2021 06:09:52

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 APR 2021 06:19:28

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

DAY 271

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

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

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

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

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

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

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

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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 ☐

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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"/>

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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="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"/>

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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 ☐

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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"/>

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 JUN 2021 00:01
Patient Cloud Close Date & Time	04 JUL 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

DAY 348

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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°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 ☐

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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 ☐

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

[Patient Cloud Open Date & Time](#)

11 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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 ☐

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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 ☐

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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"/>

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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 ☐

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	29 SEP 2021 00:01
Patient Cloud Close Date & Time	03 OCT 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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 ☐

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

[Patient Cloud Open Date & Time](#)

13 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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="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"/>

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

Patient Cloud Open Date & Time	20 OCT 2021 00:01
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Patient Cloud Close Date & Time	24 OCT 2021 23:59
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US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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"/>

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 OCT 2021 00:01
Patient Cloud Close Date & Time	31 OCT 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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 <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"/>

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

[Patient Cloud Open Date & Time](#)

10 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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°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 ☐

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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="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"/>

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

Patient Cloud Open Date & Time	15 DEC 2021 00:01
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Patient Cloud Close Date & Time	19 DEC 2021 23:59
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US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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 ☐

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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 ☐

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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 ☐

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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 ☐

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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 ☐

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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 ☐

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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 ☐

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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 ☐

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT	DAY 579
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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 ☐

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

[Patient Cloud Open Date & Time](#)

16 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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"/>

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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"/>

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 APR 2022 00:01
Patient Cloud Close Date & Time	10 APR 2022 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 APR 2022 00:01
Patient Cloud Close Date & Time	17 APR 2022 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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 ☐

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

[Patient Cloud Open Date & Time](#)

01 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUN 2022 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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="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"/>

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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 ☐

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

15 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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"/>

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 JUL 2022 00:01
Patient Cloud Close Date & Time	17 JUL 2022 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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°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 ☐

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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="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"/>

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 JUL 2022 00:01
Patient Cloud Close Date & Time	31 JUL 2022 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

Date and time of submission	
Patient Cloud Open Date & Time	10 AUG 2022 00:01
Patient Cloud Close Date & Time	14 AUG 2022 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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"/>

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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"/>

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

[Patient Cloud Open Date & Time](#)

24 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

28 AUG 2022 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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 ☐

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

DAY 761

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

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

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

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

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

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

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

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 SEP 2022 00:01
Patient Cloud Close Date & Time	11 SEP 2022 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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 ☐

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 SEP 2022 00:01
Patient Cloud Close Date & Time	18 SEP 2022 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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 ☐

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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 ☐

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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 ☐

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 OCT 2022 00:01
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Patient Cloud Close Date & Time	09 OCT 2022 23:59
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US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

16 OCT 2022 23:59

US3432081

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:31:17

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		03 MAR 2021 10:06:15

US3432081

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432081

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432081

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432081

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432081

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 4 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3432081

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432081

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 3 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3432081

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432081

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 04 Apr 2021 20:32:45

Generated On: 09 Jun 2021 17:31:17

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

Visit date (dd MMM yyyy)	30 MAR 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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US3432081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 04 Apr 2021 20:32:45

Generated On: 09 Jun 2021 17:31:17

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 MAR 2021
Time of assessment (00:00-23:59)	14:43 (24 HR)
Vital Signs Date and Time (derived)	30 MAR 2021 14:43
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	63 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432081

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 04 Apr 2021 20:32:45

Generated On: 09 Jun 2021 17:31:17

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.

US3432081

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 04 Apr 2021 20:32:45

Generated On: 09 Jun 2021 17:31:17

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 30 MAR 2021

Collection time (00:00-23:59) 14:58 (24 HR)

Collection date and time (derived) 30 MAR 2021 14:58

US3432081

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 04 Apr 2021 20:32:45

Generated On: 09 Jun 2021 17:31:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432081

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 25 Apr 2021 10:59:51

Generated On: 09 Jun 2021 17:31:17

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 5 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3432081

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 25 Apr 2021 10:59:51

Generated On: 09 Jun 2021 17:31:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432081

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

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

US3432081

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:17

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3432081

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:31:17

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"/>

US3432081

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:31:17

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3432081

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

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

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

Visit date (dd MMM yyyy)	12 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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US3432081

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

Form: Unblinding

Data signed: (b) (4) 04 Apr 2021 20:32:45

Generated On: 09 Jun 2021 17:31:17

Date of updated informed consent (dd MMM yyyy) 12 FEB 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 12 FEB 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3432081

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

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

Collection date (dd MMM yyyy)	12 FEB 2021
-------------------------------	-------------

Collection time (00:00-23:59)	09:34 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	12 FEB 2021 09:34
------------------------------------	-------------------

US3432081

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 FEB 2021
Collection time (00:00 - 23:59)	09:36
Collection Date and Time (derived)	12 FEB 2021 09:36

US3432081

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Feb 2021 00:03:27

Generated On: 09 Jun 2021 17:31:17

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3432081

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 04 Apr 2021 20:32:45

Generated On: 09 Jun 2021 17:31:17

AEID	USA-US078-2021-MRNA-1273-P30 1000009
Adverse event	APPENDICITIS
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)	20 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	21 JAN 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)	20 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	21 JAN 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 (1)

Data signed: (b) (4) 04 Apr 2021 20:32:45

Generated On: 09 Jun 2021 17:31:17

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 <input type="radio"/>
	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	

US3432081

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 04 Apr 2021 20:32:45

Generated On: 09 Jun 2021 17:31:17

PARTICIPANT STARTED
EXPERIENCING SYMPTOMS ON
20JAN2021 AND WAS
ADMITTED THAT EVENING.
PARTICIPANT HAD APPENDIX
REMOVED ON 21JAN2021 AND
WAS DISCHARGED LATER
THAT DAY. COVID TEST
20JAN21 NP, NEGATIVE. PLEASE
NOTE, SURGERY WAS DONE IN
ANOTHER COUNTRY AND
HOSPITAL RECORDS ARE
UNABLE TO BE OBTAINED.
THEY ARE ALSO IN ANOTHER
LANGUAGE.

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

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 16 Feb 2021 00:03:27

Generated On: 09 Jun 2021 17:31:17

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

Yes ☒

No ☐

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

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 25 Apr 2021 10:59:51

Generated On: 09 Jun 2021 17:31:17

Name of Medication KYLEENA IUD

Prophylaxis Yes ☒
No ☐

Indication CONTRACEPTION

Dose per administration 1

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

If dose unit is Other, specify IUD

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 CONTINUOUS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 25 Apr 2021 10:59:51

Generated On: 09 Jun 2021 17:31:17

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

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 25 Apr 2021 10:59:51

Generated On: 09 Jun 2021 17:31:17

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication INJECTION SITE PAIN AND HEADACHE

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 25 Apr 2021 10:59:51

Generated On: 09 Jun 2021 17:31:17

	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)	9 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		9 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 25 Apr 2021 10:59:51

Generated On: 09 Jun 2021 17:31:17

Name of Medication NEPROXEN

Prophylaxis Yes ☐
No ☒

Indication INJECTION SITE PAIN AND HEADACHE

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 25 Apr 2021 10:59:51

Generated On: 09 Jun 2021 17:31:17

	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)	9 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		9 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 25 Apr 2021 10:59:51

Generated On: 09 Jun 2021 17:31:17

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify VACCINATION

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 25 Apr 2021 10:59:51

Generated On: 09 Jun 2021 17:31:17

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		29 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		29 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 25 Apr 2021 10:59:51

Generated On: 09 Jun 2021 17:31:17

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication POST-APPENDECTOMY PAIN
MANAGEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 25 Apr 2021 10:59:51

Generated On: 09 Jun 2021 17:31:17

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

US3432081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Feb 2021 00:03:28

Generated On: 09 Jun 2021 17:31:17

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 16 Feb 2021 00:03:27

Generated On: 09 Jun 2021 17:31:17

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
21 JAN 2021	APPENDECTOMY	Adverse Event	

US3432081

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:31:17

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

US3432081

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:31:17

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 ☐

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Data signed: (b) (4) 04 Apr 2021 20:32:45

Generated On: 09 Jun 2021 17:31:17

SAEID	USA-US078-2021-MRNA-1273-P301000009
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

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) 04 Apr 2021 20:32:45

Generated On: 09 Jun 2021 17:31:17

SAEID	USA-US078-2021-MRNA-1273-P301000009
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)	25/JAN/2021 10:18
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

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Data signed: (b) (4) 04 Apr 2021 20:32:45

Generated On: 09 Jun 2021 17:31:17

SAEID	USA-US078-2021-MRNA-1273-P301000009
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)	09/MAR/2021 09:58
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

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Data signed: (b) (4) 04 Apr 2021 20:32:45

Generated On: 09 Jun 2021 17:31:17

SAEID	USA-US078-2021-MRNA-1273-P301000009
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)	17/MAR/2021 15:21
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

US3432081 (Prod: Brigham and Womens Hospital)

US3432081

Form: Participant Creation

Generated On: 09 Jun 2021 17:31:17

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	16 Feb 2021 00:03:29
User entered 'US3432081'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	10 Aug 2020 19:54:37

US3432081

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:31:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Monica Feeley (b) (4)	10 Aug 2020 20:51:17

US3432081

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '10 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 19:54:38

US3432081

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Clinic (Clinic)'	Monica Feeley (b) (4)	10 Aug 2020 20:51:17

US3432081

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:31:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User entered 'SCRN'	System	10 Aug 2020 20:51:17

US3432081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:17

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered (b) (6) 1991'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 19:54:39

US3432081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:17

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '28'	Julia Klopfer (b) (4)	10 Aug 2020 21:43:05

US3432081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:17

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User entered 'YEARS'	System	10 Aug 2020 21:43:05

US3432081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:17

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User entered '28'	System	10 Aug 2020 20:51:27

US3432081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:17

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Female (F)'	Julia Klopfer (b) (4)	10 Aug 2020 21:43:05

US3432081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:17

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Julia Klopfer (b) (4)	10 Aug 2020 21:43:05

US3432081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:17

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '0'	Julia Klopfer (b) (4)	10 Aug 2020 21:43:05

US3432081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:17

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '0'	Julia Klopfer (b) (4)	10 Aug 2020 21:43:05

US3432081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:17

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '0'	Julia Klopfer (b) (4)	10 Aug 2020 21:43:05

US3432081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:17

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '0'	Julia Klopfer (b) (4)	10 Aug 2020 21:43:05

US3432081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:17

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '0'	Julia Klopfer (b) (4)	10 Aug 2020 21:43:05

US3432081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:17

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'I'	Julia Klopfer (b) (4)	10 Aug 2020 21:43:05

US3432081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:17

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User closed query 'Per CDM: Ethnicity is selected as "Hispanic or Latino"; and Race is selected as "Other" However, the "Other, Specify" field matches the drop-down selection indicated in "Ethnicity" field, which is not expected. Therefore, per page 21 of CCGs, please verify data and update the "Other, Specify" field as appropriate by recording the Race(s) in which the participant self identifies, or if participant does not self-identify to any of the standard code-list choices, "Unknown" should be chosen. If patient chooses not to report or disclose Race please choose "Not Reported". Note: More than one race may be entered by checking all that apply. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 08:36:48
Query 'Per CDM: Ethnicity is selected as "Hispanic or Latino"; and Race is selected as "Other". However, the "Other, Specify" field matches the drop-down selection indicated in "Ethnicity" field, which is not expected. Therefore, per page 21 of CCGs, please verify data and update the "Other, Specify" field as appropriate by recording the Race(s) in which the participant self identifies, or if participant does not self-identify to any of the standard code-list choices, "Unknown" should be chosen. If patient chooses not to report or disclose Race please choose "Not Reported". Note: More than one race may be entered by checking all that apply. Thank you.' answered with 'Participant self-reported race as latino. Thank you.' (Site from DM).	Bruce Bausk (b) (4)	27 Oct 2020 15:26:20

US3432081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:17

If race is Other, specify

Audit	User	Time (GMT)
User opened query 'Per CDM: Ethnicity is selected as "Hispanic or Latino"; and Race is selected as "Other" However, the "Other, Specify" field matches the drop-down selection indicated in "Ethnicity" field, which is not expected. Therefore, per page 21 of CCGs, please verify data and update the "Other, Specify" field as appropriate by recording the Race(s) in which the participant self identifies, or if participant does not self-identify to any of the standard code-list choices, "Unknown" should be chosen. If patient chooses not to report or disclose Race please choose "Not Reported". Note: More than one race may be entered by checking all that apply. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 13:39:03
User closed query 'Per CDM: Thank you for your response. However, Latino is indicated in the Ethnicity field. Please consider updating to Unknown. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 13:39:03
Query 'Per CDM: Thank you for your response. However, Latino is indicated in the Ethnicity field. Please consider updating to Unknown. ' answered with 'Thank you. The participant self-reported race their race as "latino". ' (Site from DM).	Bruce Bausk (b) (4) (b) (4)	05 Oct 2020 18:23:21
User opened query 'Per CDM: Thank you for your response. However, Latino is indicated in the Ethnicity field. Please consider updating to Unknown. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 13:59:19
User closed query 'Per CDM, please specify exact race, otherwise considering updating to Unknown or explain.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 13:59:19
Query 'Per CDM, please specify exact race, otherwise considering updating to Unknown or explain.' answered with 'not recorded correctly in iMedi. Pt reported Latino' (Site from DM).	Monica Feeley (b) (4) (b) (4)	16 Sep 2020 22:33:54
User entered 'Latino' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	16 Sep 2020 22:33:31
User opened query 'Per CDM, please specify exact race, otherwise considering updating to Unknown or explain.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 08:13:19
User closed query 'Race has been reported as Other, however If race is Other, specify is missing. Please provide.' (Site from System).	System	10 Aug 2020 22:37:14

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EAB) (1725)

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Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:17

If race is Other, specify

Audit	User	Time (GMT)
User entered 'other' reason for change: Data Entry Error	Monica Feeley (b) (4)	10 Aug 2020 22:37:14
User opened query 'Race has been reported as Other, however If race is Other, specify is missing. Please provide.' (Site from System).	System	10 Aug 2020 21:43:05
User entered empty.	Julia Klopfer (b) (4)	10 Aug 2020 21:43:05

US3432081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:17

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '0'	Julia Klopfer (b) (4)	10 Aug 2020 21:43:05

US3432081

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:31:17

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '0'	Julia Klopfer (b) (4)	10 Aug 2020 21:43:05

US3432081

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:31:17

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '10 Aug 2020'	Monica Feeley (b) (4)	10 Aug 2020 20:51:27

US3432081

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User entered 'Aug 2020'	System	10 Aug 2020 20:51:27

US3432081

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User entered '2020'	System	10 Aug 2020 20:51:27

US3432081

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:31:17

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Amendment 1 (1)'	Monica Feeley (b) (4)	10 Aug 2020 20:51:27

US3432081

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Monica Feeley (b) (4)	10 Aug 2020 20:51:27

US3432081

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	Monica Feeley (b) (4)	10 Aug 2020 20:51:27

US3432081

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:31:17

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	Monica Feeley (b) (4)	10 Aug 2020 20:51:27

US3432081

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:31:17

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	Monica Feeley (b) (4)	10 Aug 2020 20:51:27

US3432081

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:31:17

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 19:54:38

US3432081

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:31:17

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User entered 'I'	System	10 Aug 2020 20:51:33

US3432081

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Monica Feeley (b) (4)	10 Aug 2020 20:51:33

US3432081

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:31:17

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Alexander Mills (b) (4)	09 Dec 2020 17:00:40
User entered 'No (N)'	Julia Klopfer (b) (4)	10 Aug 2020 21:44:15

US3432081

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:31:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 17:03:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 17:03:09
Data point term sent to Coder	System	09 Dec 2020 17:02:10
User entered 'Tonsillectomy'	Alexander Mills (b) (4)	09 Dec 2020 17:02:01

US3432081

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'un UNK 2013'	Alexander Mills (b) (4)	09 Dec 2020 17:02:01

US3432081

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:31:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '0'	Alexander Mills (b) (4)	09 Dec 2020 17:02:01

US3432081

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:31:17

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	Alexander Mills (b) (4)	09 Dec 2020 17:02:01

US3432081

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'un UNK 2013'	Alexander Mills (b) (4)	09 Dec 2020 17:02:01

US3432081

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:31:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '0'	Alexander Mills (b) (4)	09 Dec 2020 17:02:01

US3432081

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User entered 'Jan 2013'	System	09 Dec 2020 17:02:01

US3432081

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User entered '2013'	System	09 Dec 2020 17:02:01

US3432081

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User entered 'Jan 2013'	System	09 Dec 2020 17:02:01

US3432081

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User entered '2013'	System	09 Dec 2020 17:02:01

US3432081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	10 Aug 2020 21:45:30

US3432081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '10 Aug 2020'	Julia Klopfer (b) (4)	10 Aug 2020 21:45:30

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '16:00'	Julia Klopfer (b) (4)	10 Aug 2020 21:45:30

US3432081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User entered '10 Aug 2020 16:00'	System	10 Aug 2020 21:45:30

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '161' cm	Julia Klopfer (b) (4)	10 Aug 2020 21:45:30
DataPoint set to visible.	(b) (4) System	10 Aug 2020 20:51:33

US3432081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '55.9' kg	Julia Klopfer (b) (4)	10 Aug 2020 21:45:30
DataPoint set to visible.	(b) (4) System	10 Aug 2020 20:51:33

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
Amendment Manager: User entered '21.56553'	System	16 Sep 2020 23:50:38
User entered '21.6'	System	10 Aug 2020 21:45:30
DataPoint set to visible.	System	10 Aug 2020 20:51:33

US3432081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User entered 'kg/m2'	System	10 Aug 2020 21:45:30
DataPoint set to visible.	System	10 Aug 2020 20:51:33

US3432081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 19:16:34
User entered '37.2' C	Julia Klopfer (b) (4)	10 Aug 2020 21:45:30

US3432081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 11:59:29
Query 'Data is required. Please provide.' answered with 'No data is listed per (b) (6) request.' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 19:16:39
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Aug 2020 19:16:34
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 19:16:34
User entered 'Oral (Oral)'	Julia Klopfer (b) (4)	10 Aug 2020 21:45:30

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	Julia Klopfer (b) (4)	10 Aug 2020 21:45:30

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 19:16:34
User entered '54'	Julia Klopfer (b) (4)	10 Aug 2020 21:45:30

US3432081

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User entered 'bpm'	System	10 Aug 2020 21:45:30

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 19:16:34
User entered '16'	Julia Klopfer (b) (4)	10 Aug 2020 21:45:30

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User entered 'breaths/min'	System	10 Aug 2020 21:45:30

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 19:16:34
User entered '116'	Julia Klopfer (b) (4)	10 Aug 2020 21:45:30

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User entered 'mmHg'	System	10 Aug 2020 21:45:30

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 19:16:34
User entered '66'	Julia Klopfer (b) (4)	10 Aug 2020 21:45:30

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User entered 'mmHg'	System	10 Aug 2020 21:45:30

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23

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Folder: Screening

Form: Vital Signs

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[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23

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Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	10 Aug 2020 21:45:42

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Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 09:21:00
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		08 Sep 2020 22:05:14
User entered '10 Aug 2020'	Julia Klopfer (b) (4)	10 Aug 2020 21:45:42

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:31:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '10 Aug 2020'	Julia Klopfer (b) (4)	10 Aug 2020 21:46:04

US3432081

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:31:17

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	10 Aug 2020 21:46:04

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Folder: Screening

Form: Childbearing Potential

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	Julia Klopfer (b) (4)	10 Aug 2020 21:46:04

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Folder: Screening

Form: Childbearing Potential

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If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	Julia Klopfer (b) (4)	10 Aug 2020 21:46:04

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Folder: Screening

Form: Childbearing Potential

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	Julia Klopfer (b) (4)	10 Aug 2020 21:46:04

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Folder: Screening

Form: Childbearing Potential

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[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '0'	Julia Klopfer (b) (4)	10 Aug 2020 21:46:04

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Folder: Screening

Form: Childbearing Potential

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	Julia Klopfer (b) (4)	10 Aug 2020 21:46:04

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Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:31:17

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '0'	Julia Klopfer (b) (4)	10 Aug 2020 21:46:04

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Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:31:17

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Monica Feeley (b) (4)	10 Aug 2020 22:35:44

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Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:31:17

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '10 Aug 2020'	Monica Feeley (b) (4)	10 Aug 2020 22:35:44

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Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:31:17

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Urine (URINE)'	Monica Feeley (b) (4)	10 Aug 2020 22:35:44

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Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:31:17

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Negative (NEGATIVE)'	Monica Feeley (b) (4)	10 Aug 2020 22:35:44

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Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:31:17

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	Monica Feeley (b) (4)	10 Aug 2020 22:35:44

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Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:31:17

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	Monica Feeley (b) (4)	10 Aug 2020 22:35:44

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Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:31:17

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	Monica Feeley (b) (4)	10 Aug 2020 22:35:44

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Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User entered empty.	System	10 Aug 2020 22:35:44

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	10 Aug 2020 21:46:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	Julia Klopfer (b) (4)	10 Aug 2020 21:46:58

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	Julia Klopfer (b) (4)	10 Aug 2020 21:46:58

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	Julia Klopfer (b) (4)	10 Aug 2020 21:46:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:17

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	Julia Klopfer (b) (4)	10 Aug 2020 21:46:58

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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)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	Julia Klopfer (b) (4)	10 Aug 2020 21:46:58

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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)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	Julia Klopfer (b) (4)	10 Aug 2020 21:46:58

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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)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	Julia Klopfer (b) (4)	10 Aug 2020 21:46:58

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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)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	Julia Klopfer (b) (4)	10 Aug 2020 21:46:58

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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)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	Julia Klopfer (b) (4)	10 Aug 2020 21:46:58

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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)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	Julia Klopfer (b) (4)	10 Aug 2020 21:46:58

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	Julia Klopfer (b) (4)	10 Aug 2020 21:46:58

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	Julia Klopfer (b) (4)	10 Aug 2020 21:46:58

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '0'	Julia Klopfer (b) (4)	10 Aug 2020 21:46:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:17

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '0'	Julia Klopfer (b) (4)	10 Aug 2020 21:46:58

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:17

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '0'	Julia Klopfer (b) (4)	10 Aug 2020 21:46:58

US3432081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:17

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '0'	Julia Klopfer (b) (4)	10 Aug 2020 21:46:58

US3432081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:17

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '0'	Julia Klopfer (b) (4)	10 Aug 2020 21:46:58

US3432081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:17

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'I'	Julia Klopfer (b) (4)	10 Aug 2020 21:46:58

US3432081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:17

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '0'	Julia Klopfer (b) (4)	10 Aug 2020 21:46:58

US3432081

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:31:17

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	Julia Klopfer (b) (4)	10 Aug 2020 21:46:58

US3432081

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:31:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Monica Feeley (b) (4)	10 Aug 2020 20:51:45

US3432081

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '10 Aug 2020'	Monica Feeley (b) (4)	10 Aug 2020 20:51:45

US3432081

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Clinic (Clinic)'	Monica Feeley (b) (4)	10 Aug 2020 20:51:45

US3432081

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:31:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'VISIT1'	System	10 Aug 2020 20:51:45

US3432081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '10 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 20:14:24

US3432081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:31:17

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:24:24
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:24:24
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Aug 2020 20:14:24
User entered '102732' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 20:14:24

US3432081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:31:17

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 20:14:24

US3432081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:31:17

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)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	Julia Klopfer (b) (4)	10 Aug 2020 21:47:57

US3432081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:31:17

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)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	Julia Klopfer (b) (4)	10 Aug 2020 21:47:57

US3432081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:31:17

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	Julia Klopfer (b) (4)	10 Aug 2020 21:47:57

US3432081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:31:17

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	Julia Klopfer (b) (4)	10 Aug 2020 21:47:57

US3432081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:31:17

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	Julia Klopfer (b) (4)	10 Aug 2020 21:47:57

US3432081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:31:17

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered missing code ND - Not Done.	Julia Klopfer (b) (4)	10 Aug 2020 21:51:14

US3432081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:31:17

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered missing code ND - Not Done.	Julia Klopfer (b) (4)	10 Aug 2020 21:51:14

US3432081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:31:17

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered missing code ND - Not Done.	Julia Klopfer (b) (4)	10 Aug 2020 21:51:14

US3432081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:31:17

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered missing code ND - Not Done.	Julia Klopfer (b) (4)	10 Aug 2020 21:51:14

US3432081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User accepted default value 'Pre-Dose (PREDOSE)'	Julia Klopfer (b) (4) (b) (4)	10 Aug 2020 21:51:14

US3432081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	10 Aug 2020 21:51:14

US3432081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '10 Aug 2020'	Julia Klopfer (b) (4)	10 Aug 2020 21:51:14

US3432081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '16:00'	Julia Klopfer (b) (4)	10 Aug 2020 21:51:14

US3432081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered '10 Aug 2020 16:00'	System	10 Aug 2020 21:51:14

US3432081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '37.2' C	Julia Klopfer (b) (4)	10 Aug 2020 21:51:14

US3432081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Oral (Oral)'	Julia Klopfer (b) (4)	10 Aug 2020 21:51:14

US3432081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	Julia Klopfer (b) (4)	10 Aug 2020 21:51:14

US3432081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '54'	Julia Klopfer (b) (4)	10 Aug 2020 21:51:14

US3432081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'bpm'	System	10 Aug 2020 21:51:14

US3432081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '16'	Julia Klopfer (b) (4)	10 Aug 2020 21:51:14

US3432081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'breaths/min'	System	10 Aug 2020 21:51:14

US3432081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '116'	Julia Klopfer (b) (4)	10 Aug 2020 21:51:14

US3432081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'mmHg'	System	10 Aug 2020 21:51:14

US3432081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '66'	Julia Klopfer (b) (4)	10 Aug 2020 21:51:14

US3432081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'mmHg'	System	10 Aug 2020 21:51:14

US3432081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:31:17

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered missing code ND - Not Done.	Julia Klopfer (b) (4)	10 Aug 2020 21:51:14

US3432081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:31:17

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered missing code ND - Not Done.	Julia Klopfer (b) (4)	10 Aug 2020 21:51:14

US3432081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User accepted default value 'Post-Dose (POSTDOSE)'	Julia Klopfer (b) (4) (b) (4)	10 Aug 2020 21:51:14

US3432081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	10 Aug 2020 21:51:14

US3432081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '10 Aug 2020'	Julia Klopfer (b) (4)	10 Aug 2020 21:51:14

US3432081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 10:53:25
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Per protocol, 30 mins after vaccine' (Site from System).	Julia Klopfer (b) (4)	10 Aug 2020 21:51:36
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		10 Aug 2020 21:51:14
User entered '17:08'	Julia Klopfer (b) (4)	10 Aug 2020 21:51:14

US3432081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered '10 Aug 2020 17:08'	System	10 Aug 2020 21:51:14

US3432081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '37.0' C	Julia Klopfer (b) (4)	10 Aug 2020 21:51:14

US3432081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Oral (Oral)'	Julia Klopfer (b) (4)	10 Aug 2020 21:51:14

US3432081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	Julia Klopfer (b) (4)	10 Aug 2020 21:51:14

US3432081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '55'	Julia Klopfer (b) (4)	10 Aug 2020 21:51:14

US3432081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'bpm'	System	10 Aug 2020 21:51:14

US3432081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '14'	Julia Klopfer (b) (4)	10 Aug 2020 21:51:14

US3432081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'breaths/min'	System	10 Aug 2020 21:51:14

US3432081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '113'	Julia Klopfer (b) (4)	10 Aug 2020 21:51:14

US3432081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'mmHg'	System	10 Aug 2020 21:51:14

US3432081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '63'	Julia Klopfer (b) (4)	10 Aug 2020 21:51:14

US3432081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'mmHg'	System	10 Aug 2020 21:51:14

US3432081

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	Julia Klopfer (b) (4)	10 Aug 2020 21:51:46

US3432081

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	Julia Klopfer (b) (4)	10 Aug 2020 21:51:46

US3432081

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:31:17

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User closed query 'Per CDM, test with the same date reported at Screening. Please check. If duplicate information, please record test at Visit 1 Day 1 as not performed, otherwise explain.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 07:43:30
Query 'Per CDM, test with the same date reported at Screening. Please check. If duplicate information, please record test at Visit 1 Day 1 as not performed, otherwise explain.' answered with 'This is against EDC guidelines' (Site from DM).	Alexander Mills (b) (4)	22 Oct 2020 15:22:47
User entered 'No (N)' reason for change: Data Entry Error	Alexander Mills (b) (4)	22 Oct 2020 15:22:12
User opened query 'Per CDM, test with the same date reported at Screening. Please check. If duplicate information, please record test at Visit 1 Day 1 as not performed, otherwise explain.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 13:10:49
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	10 Aug 2020 21:52:00

US3432081

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:31:17

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Oct 2020 15:22:12
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Oct 2020 15:21:54
User entered empty; reason for change Data Entry Error	Alexander Mills (b) (4)	22 Oct 2020 15:21:54
User entered '10 Aug 2020'	Julia Klopfer (b) (4)	10 Aug 2020 21:52:00

US3432081

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:31:17

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Oct 2020 15:22:12
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Oct 2020 15:21:54
User entered empty; reason for change Data Entry Error	Alexander Mills (b) (4)	22 Oct 2020 15:21:54
User entered 'Urine (URINE)'	Julia Klopfer (b) (4)	10 Aug 2020 21:52:00

US3432081

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:31:17

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User closed query 'Data is required. Please provide.' (Site from System).	System	22 Oct 2020 15:22:12
User opened query 'Data is required. Please provide.' (Site from System).	System	22 Oct 2020 15:21:54
User entered empty; reason for change Data Entry Error	Alexander Mills (b) (4)	22 Oct 2020 15:21:54
User entered 'Negative (NEGATIVE)'	Julia Klopfer (b) (4)	10 Aug 2020 21:52:00

US3432081

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:31:17

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User closed query 'Per CDM: A response Yes/No is required for this field. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 08:03:37
Query 'Per CDM: A response Yes/No is required for this field. Please update accordingly. ' answered with 'updated' (Site from DM).	Julia Klopfer (b) (4)	05 Nov 2020 20:58:32
User entered 'No (N)' reason for change: Data Entry Error	Julia Klopfer (b) (4)	05 Nov 2020 20:58:21
User opened query 'Per CDM: A response Yes/No is required for this field. Please update accordingly. ' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 07:43:27
User entered empty; reason for change Data Entry Error	Alexander Mills (b) (4)	22 Oct 2020 15:21:54
User entered 'No (N)'	Julia Klopfer (b) (4)	10 Aug 2020 21:52:00

US3432081

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:31:17

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	Julia Klopfer (b) (4)	10 Aug 2020 21:52:00

US3432081

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:31:17

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	Julia Klopfer (b) (4)	10 Aug 2020 21:52:00

US3432081

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered empty.	System	10 Aug 2020 21:52:00

US3432081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:17

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Monica Feeley (b) (4)	10 Aug 2020 20:57:28

US3432081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:17

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	Monica Feeley (b) (4)	10 Aug 2020 20:57:28

US3432081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:17

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)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	Monica Feeley (b) (4)	10 Aug 2020 20:57:28

US3432081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:17

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'MRNA-1273 OR PLACEBO'	System	10 Aug 2020 20:57:28

US3432081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:17

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '10 Aug 2020'	Monica Feeley (b) (4)	10 Aug 2020 20:57:28

US3432081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:17

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '16:37'	Monica Feeley (b) (4)	10 Aug 2020 20:57:28

US3432081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:17

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered '10 Aug 2020 16:37'	System	10 Aug 2020 20:57:28

US3432081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:17

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Left Arm (LEFT ARM)'	Monica Feeley (b) (4)	10 Aug 2020 20:57:28

US3432081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:17

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'ONCE'	System	10 Aug 2020 20:57:28

US3432081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:31:17

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'INTRAMUSCULAR'	System	10 Aug 2020 20:57:28

US3432081

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Monica Feeley (b) (4)	10 Aug 2020 21:48:52

US3432081

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '10 Aug 2020'	Monica Feeley (b) (4)	10 Aug 2020 21:48:52

US3432081

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '16:15'	Monica Feeley (b) (4)	10 Aug 2020 21:48:52

US3432081

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered '10 Aug 2020 16:15'	System	10 Aug 2020 21:48:52

US3432081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:31:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '10 Aug 2020'	Monica Feeley (b) (4)	10 Aug 2020 21:49:14

US3432081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:31:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Monica Feeley (b) (4) (b) (4)	10 Aug 2020 21:49:14

US3432081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:31:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Monica Feeley (b) (4)	10 Aug 2020 21:49:14

US3432081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:31:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '16:20'	Monica Feeley (b) (4)	10 Aug 2020 21:49:14

US3432081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered '10 Aug 2020 16:20'	System	10 Aug 2020 21:49:14

US3432081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:31:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Monica Feeley (b) (4) (b) (4)	10 Aug 2020 21:49:14

US3432081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:31:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	Monica Feeley (b) (4)	10 Aug 2020 21:49:14

US3432081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:31:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	Monica Feeley (b) (4)	10 Aug 2020 21:49:14

US3432081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered empty.	System	10 Aug 2020 21:49:14

US3432081

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:31:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	10 Aug 2020 21:52:17

US3432081

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:31:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'I'	System	10 Aug 2020 21:52:17

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-10T17:10:58', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'edeb8e24-56f6-4368-a3df-cb21876dab75' User entered 'Yes (Y)'	System	10 Aug 2020 21:11:22
	System	10 Aug 2020 21:11:22

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-10T17:11:05', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'edeb8e24-56f6-4368-a3df-cb21876dab75'	System	10 Aug 2020 21:11:22
User entered '98.6'	System	10 Aug 2020 21:11:22

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-10T17:11:08', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'edeb8e24-56f6-4368-a3df-cb21876dab75'	System	10 Aug 2020 21:11:22
User entered 'No (N)'	System	10 Aug 2020 21:11:22

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-10T17:11:20', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'edeb8e24-56f6-4368-a3df-cb21876dab75'	System	10 Aug 2020 21:11:22
User entered '10 Aug 2020 17:11'	System	10 Aug 2020 21:11:22

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '10 Aug 2020 16:57'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '10 Aug 2020 19:27'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-10T20:33:36', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'e5b75a13-9d40-4dc6-b46f-f6ba053989c3' User entered 'Yes (Y)'	System	11 Aug 2020 00:33:53
	System	11 Aug 2020 00:33:53

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-10T20:33:41', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'e5b75a13-9d40-4dc6-b46f-f6ba053989c3' User entered '96.5'	System	11 Aug 2020 00:33:53
	System	11 Aug 2020 00:33:53

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-10T20:33:45', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'e5b75a13-9d40-4dc6-b46f-f6ba053989c3'	System	11 Aug 2020 00:33:53
User entered 'No (N)'	System	11 Aug 2020 00:33:53

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-10T20:33:49', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'e5b75a13-9d40-4dc6-b46f-f6ba053989c3' User entered '10 Aug 2020 20:33'	System	11 Aug 2020 00:33:53
	System	11 Aug 2020 00:33:53

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '10 Aug 2020 20:22'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered 'Day 2'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-11T13:01:42', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '083dbe74-3cc6-4183-b9c5-65172f49bb1a' User entered 'Yes (Y)'	System	12 Aug 2020 00:51:00
	System	12 Aug 2020 00:51:00

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-11T13:01:48', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '083dbe74-3cc6-4183-b9c5-65172f49bb1a' User entered '96.2'	System	12 Aug 2020 00:51:00
	System	12 Aug 2020 00:51:00

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-11T13:01:51', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '083dbe74-3cc6-4183-b9c5-65172f49bb1a' User entered 'No (N)'	System	12 Aug 2020 00:51:00
	System	12 Aug 2020 00:51:00

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-11T13:01:54', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '083dbe74-3cc6-4183-b9c5-65172f49bb1a' User entered '11 Aug 2020 13:01'	System	12 Aug 2020 00:51:00
	System	12 Aug 2020 00:51:00

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered 'Day 3'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-12T15:07:22', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'f3183e53-855d-48a1-9c8c-33d37d412e26' User entered 'Yes (Y)'	System	12 Aug 2020 19:08:29
	System	12 Aug 2020 19:08:29

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-12T15:08:20', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'f3183e53-855d-48a1-9c8c-33d37d412e26' User entered '94.9'	System	12 Aug 2020 19:08:29
	System	12 Aug 2020 19:08:29

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-12T15:08:22', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'f3183e53-855d-48a1-9c8c-33d37d412e26'	System	12 Aug 2020 19:08:29
User entered 'No (N)'	System	12 Aug 2020 19:08:29

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-12T15:08:26', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'f3183e53-855d-48a1-9c8c-33d37d412e26'	System	12 Aug 2020 19:08:29
User entered '12 Aug 2020 15:08'	System	12 Aug 2020 19:08:29

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered 'Day 4'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-13T16:35:08', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '4f78d205-592c-41bf-9307-70739d3a1199'	System	13 Aug 2020 20:35:51
User entered 'Yes (Y)'	System	13 Aug 2020 20:35:51

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-13T16:35:40', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '4f78d205-592c-41bf-9307-70739d3a1199' User entered '96.8'	System	13 Aug 2020 20:35:51
	System	13 Aug 2020 20:35:51

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-13T16:35:46', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '4f78d205-592c-41bf-9307-70739d3a1199'	System	13 Aug 2020 20:35:51
User entered 'No (N)'	System	13 Aug 2020 20:35:51

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-13T16:35:49', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '4f78d205-592c-41bf-9307-70739d3a1199'	System	13 Aug 2020 20:35:51
User entered '13 Aug 2020 16:35'	System	13 Aug 2020 20:35:51

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered 'Day 5'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-14T15:01:26', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '0af6d315-63a8-415b-9b5c-a7dc9f669ef8'	System	14 Aug 2020 19:01:59
User entered 'Yes (Y)'	System	14 Aug 2020 19:01:59

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-14T15:01:37', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '0af6d315-63a8-415b-9b5c-a7dc9f669ef8' User entered '96.0'	System	14 Aug 2020 19:01:59
	System	14 Aug 2020 19:01:59

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-14T15:01:48', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '0af6d315-63a8-415b-9b5c-a7dc9f669ef8'	System	14 Aug 2020 19:01:59
User entered 'No (N)'	System	14 Aug 2020 19:01:59

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-14T15:01:58', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '0af6d315-63a8-415b-9b5c-a7dc9f669ef8' User entered '14 Aug 2020 15:01'	System	14 Aug 2020 19:01:59
	System	14 Aug 2020 19:01:59

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered 'Day 6'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-15T15:24:09', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'd20517a5-5216-459c-9b89-b905c144b34b' User entered 'Yes (Y)'	System	15 Aug 2020 19:24:36
	System	15 Aug 2020 19:24:36

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-15T15:24:14', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'd20517a5-5216-459c-9b89-b905c144b34b' User entered '96.0'	System	15 Aug 2020 19:24:36
	System	15 Aug 2020 19:24:36

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-15T15:24:32', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'd20517a5-5216-459c-9b89-b905c144b34b'	System	15 Aug 2020 19:24:36
User entered 'No (N)'	System	15 Aug 2020 19:24:36

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-15T15:24:35', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'd20517a5-5216-459c-9b89-b905c144b34b' User entered '15 Aug 2020 15:24'	System	15 Aug 2020 19:24:36
	System	15 Aug 2020 19:24:36

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered 'Day 7'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-16T17:30:36', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'e51ff5d4-cf79-40df-9f96-bfd82a924f21'	System	16 Aug 2020 21:30:56
User entered 'Yes (Y)'	System	16 Aug 2020 21:30:56

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-16T17:30:49', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'e51ff5d4-cf79-40df-9f96-bfd82a924f21'	System	16 Aug 2020 21:30:56
User entered '95.6'	System	16 Aug 2020 21:30:56

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-16T17:30:51', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'e51ff5d4-cf79-40df-9f96-bfd82a924f21'	System	16 Aug 2020 21:30:56
User entered 'No (N)'	System	16 Aug 2020 21:30:56

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-16T17:30:53', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'e51ff5d4-cf79-40df-9f96-bfd82a924f21'	System	16 Aug 2020 21:30:56
User entered '16 Aug 2020 17:30'	System	16 Aug 2020 21:30:56

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-10T17:12:13', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '93e57013-b4cf-4963-8252-39aeb7a29e5a' User entered 'None (1)'	System	10 Aug 2020 21:12:30
	System	10 Aug 2020 21:12:30

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-10T17:12:18', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '93e57013-b4cf-4963-8252-39aeb7a29e5a'	System	10 Aug 2020 21:12:30
User entered 'No (N)'	System	10 Aug 2020 21:12:30

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-10T17:12:21', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '93e57013-b4cf-4963-8252-39aeb7a29e5a' User entered 'No (N)'	System	10 Aug 2020 21:12:30
	System	10 Aug 2020 21:12:30

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-10T17:12:25', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '93e57013-b4cf-4963-8252-39aeb7a29e5a' User entered 'None (1)'	System	10 Aug 2020 21:12:30
	System	10 Aug 2020 21:12:30

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-10T17:12:28', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '93e57013-b4cf-4963-8252-39aeb7a29e5a' User entered '10 Aug 2020 17:12'	System	10 Aug 2020 21:12:30
	System	10 Aug 2020 21:12:30

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '10 Aug 2020 16:57'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '10 Aug 2020 19:27'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-10T20:33:54', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'eaa86aa1-cb55-4d04-a0bb-f04ca964ea24'	System	11 Aug 2020 00:34:12
User entered 'None (1)'	System	11 Aug 2020 00:34:12

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-10T20:33:58', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'eaa86aa1-cb55-4d04-a0bb-f04ca964ea24' User entered 'No (N)'	System	11 Aug 2020 00:34:12
	System	11 Aug 2020 00:34:12

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-10T20:34:03', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'eaa86aa1-cb55-4d04-a0bb-f04ca964ea24'	System	11 Aug 2020 00:34:12
User entered 'No (N)'	System	11 Aug 2020 00:34:12

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-10T20:34:08', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'eaa86aa1-cb55-4d04-a0bb-f04ca964ea24'	System	11 Aug 2020 00:34:12
User entered 'None (1)'	System	11 Aug 2020 00:34:12

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-10T20:34:11', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'eaa86aa1-cb55-4d04-a0bb-f04ca964ea24'	System	11 Aug 2020 00:34:12
User entered '10 Aug 2020 20:34'	System	11 Aug 2020 00:34:12

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '10 Aug 2020 20:22'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered 'Day 2'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-11T13:00:50', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '476e3063-f399-4f08-ad71-9b395667ed5b'	System	12 Aug 2020 00:50:57
User entered 'Does not interfere with activity (2)'	System	12 Aug 2020 00:50:57

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-11T13:00:56', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '476e3063-f399-4f08-ad71-9b395667ed5b' User entered 'No (N)'	System	12 Aug 2020 00:50:57
	System	12 Aug 2020 00:50:57

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-11T13:01:06', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '476e3063-f399-4f08-ad71-9b395667ed5b' User entered 'No (N)'	System	12 Aug 2020 00:50:57
	System	12 Aug 2020 00:50:57

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-11T13:01:09', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '476e3063-f399-4f08-ad71-9b395667ed5b' User entered 'None (1)'	System	12 Aug 2020 00:50:57
	System	12 Aug 2020 00:50:57

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-11T13:01:12', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '476e3063-f399-4f08-ad71-9b395667ed5b' User entered '11 Aug 2020 13:01'	System	12 Aug 2020 00:50:57
	System	12 Aug 2020 00:50:57

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered 'Day 3'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-12T15:06:12', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '5ecfe2e2-e66e-4a9d-a0d0-cb4c977bc1ee' User entered 'Does not interfere with activity (2)'	System	12 Aug 2020 19:06:42
	System	12 Aug 2020 19:06:42

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-12T15:06:14', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '5ecfe2e2-e66e-4a9d-a0d0-cb4c977bc1ee'	System	12 Aug 2020 19:06:42
User entered 'No (N)'	System	12 Aug 2020 19:06:42

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-12T15:06:22', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '5ecfe2e2-e66e-4a9d-a0d0-cb4c977bc1ee'	System	12 Aug 2020 19:06:42
User entered 'No (N)'	System	12 Aug 2020 19:06:42

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-12T15:06:35', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '5ecfe2e2-e66e-4a9d-a0d0-cb4c977bc1ee'	System	12 Aug 2020 19:06:42
User entered 'None (1)'	System	12 Aug 2020 19:06:42

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-12T15:06:40', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '5ecfe2e2-e66e-4a9d-a0d0-cb4c977bc1ee' User entered '12 Aug 2020 15:06'	System	12 Aug 2020 19:06:42
	System	12 Aug 2020 19:06:42

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered 'Day 4'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-13T16:34:43', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '20928c47-2f12-4471-b1dc-98718d622296'	System	13 Aug 2020 20:34:53
User entered 'None (1)'	System	13 Aug 2020 20:34:53

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-13T16:34:45', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '20928c47-2f12-4471-b1dc-98718d622296'	System	13 Aug 2020 20:34:53
User entered 'No (N)'	System	13 Aug 2020 20:34:53

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-13T16:34:47', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '20928c47-2f12-4471-b1dc-98718d622296'	System	13 Aug 2020 20:34:53
User entered 'No (N)'	System	13 Aug 2020 20:34:53

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-13T16:34:49', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '20928c47-2f12-4471-b1dc-98718d622296'	System	13 Aug 2020 20:34:53
User entered 'None (1)'	System	13 Aug 2020 20:34:53

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-13T16:34:51', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '20928c47-2f12-4471-b1dc-98718d622296'	System	13 Aug 2020 20:34:53
User entered '13 Aug 2020 16:34'	System	13 Aug 2020 20:34:53

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered 'Day 5'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-14T15:07:54', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '39d0e5a7-bd21-48fc-84c9-6589bbdee0d3' User entered 'None (1)'	System	14 Aug 2020 19:14:25
	System	14 Aug 2020 19:14:25

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-14T15:12:43', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '39d0e5a7-bd21-48fc-84c9-6589bbdee0d3' User entered 'No (N)'	System	14 Aug 2020 19:14:25
	System	14 Aug 2020 19:14:25

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-14T15:13:33', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '39d0e5a7-bd21-48fc-84c9-6589bbdee0d3' User entered 'No (N)'	System	14 Aug 2020 19:14:25
	System	14 Aug 2020 19:14:25

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-14T15:14:19', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '39d0e5a7-bd21-48fc-84c9-6589bbdee0d3'	System	14 Aug 2020 19:14:25
User entered 'None (1)'	System	14 Aug 2020 19:14:25

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-14T15:14:21', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '39d0e5a7-bd21-48fc-84c9-6589bbdee0d3' User entered '14 Aug 2020 15:14'	System	14 Aug 2020 19:14:25
	System	14 Aug 2020 19:14:25

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered 'Day 6'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-15T15:24:38', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'cd85f96d-6c5d-49ba-bee7-a1d33375f73a' User entered 'None (1)'	System	15 Aug 2020 19:24:48
	System	15 Aug 2020 19:24:48

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-15T15:24:41', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'cd85f96d-6c5d-49ba-bee7-a1d33375f73a' User entered 'No (N)'	System	15 Aug 2020 19:24:48
	System	15 Aug 2020 19:24:48

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-15T15:24:43', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'cd85f96d-6c5d-49ba-bee7-a1d33375f73a' User entered 'No (N)'	System	15 Aug 2020 19:24:48
	System	15 Aug 2020 19:24:48

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-15T15:24:44', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'cd85f96d-6c5d-49ba-bee7-a1d33375f73a' User entered 'None (1)'	System	15 Aug 2020 19:24:48
	System	15 Aug 2020 19:24:48

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-15T15:24:46', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'cd85f96d-6c5d-49ba-bee7-a1d33375f73a' User entered '15 Aug 2020 15:24'	System	15 Aug 2020 19:24:48
	System	15 Aug 2020 19:24:48

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered 'Day 7'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-16T17:30:23', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '79a9aa5c-f468-429e-b14a-d6242e5eccc8'	System	16 Aug 2020 21:30:33
User entered 'None (1)'	System	16 Aug 2020 21:30:33

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-16T17:30:25', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '79a9aa5c-f468-429e-b14a-d6242e5eccc8'	System	16 Aug 2020 21:30:33
User entered 'No (N)'	System	16 Aug 2020 21:30:33

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-16T17:30:27', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '79a9aa5c-f468-429e-b14a-d6242e5eccc8'	System	16 Aug 2020 21:30:33
User entered 'No (N)'	System	16 Aug 2020 21:30:33

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-16T17:30:29', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '79a9aa5c-f468-429e-b14a-d6242e5eccc8'	System	16 Aug 2020 21:30:33
User entered 'None (1)'	System	16 Aug 2020 21:30:33

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-16T17:30:31', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '79a9aa5c-f468-429e-b14a-d6242e5eccc8' User entered '16 Aug 2020 17:30'	System	16 Aug 2020 21:30:33
	System	16 Aug 2020 21:30:33

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-10T17:11:44', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '4ce8bb2c-3ebf-49c3-8f07-99c6ba61e399'	System	10 Aug 2020 21:12:12
User entered 'None (0)'	System	10 Aug 2020 21:12:12

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-10T17:11:48', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '4ce8bb2c-3ebf-49c3-8f07-99c6ba61e399'	System	10 Aug 2020 21:12:12
User entered 'None (0)'	System	10 Aug 2020 21:12:12

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-10T17:11:52', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '4ce8bb2c-3ebf-49c3-8f07-99c6ba61e399' User entered 'None (0)'	System	10 Aug 2020 21:12:12
	System	10 Aug 2020 21:12:12

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-10T17:11:54', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '4ce8bb2c-3ebf-49c3-8f07-99c6ba61e399' User entered 'None (0)'	System	10 Aug 2020 21:12:12
	System	10 Aug 2020 21:12:12

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-10T17:11:56', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '4ce8bb2c-3ebf-49c3-8f07-99c6ba61e399' User entered 'None (0)'	System	10 Aug 2020 21:12:12
	System	10 Aug 2020 21:12:12

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-10T17:11:58', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '4ce8bb2c-3ebf-49c3-8f07-99c6ba61e399'	System	10 Aug 2020 21:12:12
User entered 'None (0)'	System	10 Aug 2020 21:12:12

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-10T17:12:03', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '4ce8bb2c-3ebf-49c3-8f07-99c6ba61e399'	System	10 Aug 2020 21:12:12
User entered 'No (N)'	System	10 Aug 2020 21:12:12

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-10T17:12:08', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '4ce8bb2c-3ebf-49c3-8f07-99c6ba61e399'	System	10 Aug 2020 21:12:12
User entered '10 Aug 2020 17:12'	System	10 Aug 2020 21:12:12

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '10 Aug 2020 16:57'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '10 Aug 2020 19:27'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-10T20:34:16', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'd3c8c59f-e8b4-44d8-ad11-a9b83da43197' User entered 'None (0)'	System	11 Aug 2020 00:34:35
	System	11 Aug 2020 00:34:35

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-10T20:34:18', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'd3c8c59f-e8b4-44d8-ad11-a9b83da43197' User entered 'None (0)'	System	11 Aug 2020 00:34:35
	System	11 Aug 2020 00:34:35

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-10T20:34:19', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'd3c8c59f-e8b4-44d8-ad11-a9b83da43197' User entered 'None (0)'	System	11 Aug 2020 00:34:35
	System	11 Aug 2020 00:34:35

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-10T20:34:22', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'd3c8c59f-e8b4-44d8-ad11-a9b83da43197' User entered 'None (0)'	System	11 Aug 2020 00:34:35
	System	11 Aug 2020 00:34:35

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-10T20:34:25', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'd3c8c59f-e8b4-44d8-ad11-a9b83da43197' User entered 'None (0)'	System	11 Aug 2020 00:34:35
	System	11 Aug 2020 00:34:35

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-10T20:34:26', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'd3c8c59f-e8b4-44d8-ad11-a9b83da43197' User entered 'None (0)'	System	11 Aug 2020 00:34:35
	System	11 Aug 2020 00:34:35

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-10T20:34:29', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'd3c8c59f-e8b4-44d8-ad11-a9b83da43197'	System	11 Aug 2020 00:34:35
User entered 'No (N)'	System	11 Aug 2020 00:34:35

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-10T20:34:31', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'd3c8c59f-e8b4-44d8-ad11-a9b83da43197'	System	11 Aug 2020 00:34:35
User entered '10 Aug 2020 20:34'	System	11 Aug 2020 00:34:35

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '10 Aug 2020 20:22'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered 'Day 2'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-11T13:01:16', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'd3965752-5d86-4141-977d-4ba71f4c56e6' User entered 'None (0)'	System	12 Aug 2020 00:51:00
	System	12 Aug 2020 00:51:00

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-11T13:01:20', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'd3965752-5d86-4141-977d-4ba71f4c56e6' User entered 'None (0)'	System	12 Aug 2020 00:51:00
	System	12 Aug 2020 00:51:00

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-11T13:01:22', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'd3965752-5d86-4141-977d-4ba71f4c56e6' User entered 'None (0)'	System	12 Aug 2020 00:51:00
	System	12 Aug 2020 00:51:00

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-11T13:01:26', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'd3965752-5d86-4141-977d-4ba71f4c56e6' User entered 'None (0)'	System	12 Aug 2020 00:51:00
	System	12 Aug 2020 00:51:00

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-11T13:01:28', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'd3965752-5d86-4141-977d-4ba71f4c56e6' User entered 'None (0)'	System	12 Aug 2020 00:51:00
	System	12 Aug 2020 00:51:00

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-11T13:01:30', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'd3965752-5d86-4141-977d-4ba71f4c56e6' User entered 'None (0)'	System	12 Aug 2020 00:51:00
	System	12 Aug 2020 00:51:00

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-11T13:01:32', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'd3965752-5d86-4141-977d-4ba71f4c56e6' User entered 'No (N)'	System	12 Aug 2020 00:51:00
	System	12 Aug 2020 00:51:00

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-11T13:01:34', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'd3965752-5d86-4141-977d-4ba71f4c56e6' User entered '11 Aug 2020 13:01'	System	12 Aug 2020 00:51:00
	System	12 Aug 2020 00:51:00

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered 'Day 3'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-12T15:07:00', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'eac65539-2f13-4206-9c73-aaa1568ba104' User entered 'None (0)'	System	12 Aug 2020 19:07:19
	System	12 Aug 2020 19:07:19

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-12T15:07:08', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'eac65539-2f13-4206-9c73-aaa1568ba104' User entered 'None (0)'	System	12 Aug 2020 19:07:19
	System	12 Aug 2020 19:07:19

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-12T15:07:05', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'eac65539-2f13-4206-9c73-aaa1568ba104' User entered 'None (0)'	System	12 Aug 2020 19:07:19
	System	12 Aug 2020 19:07:19

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-12T15:07:09', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'eac65539-2f13-4206-9c73-aaa1568ba104' User entered 'None (0)'	System	12 Aug 2020 19:07:19
	System	12 Aug 2020 19:07:19

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-12T15:07:11', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'eac65539-2f13-4206-9c73-aaa1568ba104' User entered 'None (0)'	System	12 Aug 2020 19:07:19
	System	12 Aug 2020 19:07:19

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-12T15:07:13', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'eac65539-2f13-4206-9c73-aaa1568ba104' User entered 'None (0)'	System	12 Aug 2020 19:07:19
	System	12 Aug 2020 19:07:19

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-12T15:07:15', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'eac65539-2f13-4206-9c73-aaa1568ba104'	System	12 Aug 2020 19:07:19
User entered 'No (N)'	System	12 Aug 2020 19:07:19

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-12T15:07:17', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'eac65539-2f13-4206-9c73-aaa1568ba104' User entered '12 Aug 2020 15:07'	System	12 Aug 2020 19:07:19
	System	12 Aug 2020 19:07:19

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered 'Day 4'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-13T16:34:54', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'c8a85787-5f98-484b-8b34-cccefa3a4b3a' User entered 'None (0)'	System	13 Aug 2020 20:35:07
	System	13 Aug 2020 20:35:07

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-13T16:34:56', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'c8a85787-5f98-484b-8b34-cccefa3a4b3a' User entered 'None (0)'	System	13 Aug 2020 20:35:07
	System	13 Aug 2020 20:35:07

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-13T16:34:57', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'c8a85787-5f98-484b-8b34-cccefa3a4b3a' User entered 'None (0)'	System	13 Aug 2020 20:35:07
	System	13 Aug 2020 20:35:07

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-13T16:34:58', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'c8a85787-5f98-484b-8b34-cccefa3a4b3a' User entered 'None (0)'	System	13 Aug 2020 20:35:07
	System	13 Aug 2020 20:35:07

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-13T16:34:59', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'c8a85787-5f98-484b-8b34-cccefa3a4b3a' User entered 'None (0)'	System	13 Aug 2020 20:35:07
	System	13 Aug 2020 20:35:07

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-13T16:35:01', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'c8a85787-5f98-484b-8b34-cccefa3a4b3a' User entered 'None (0)'	System	13 Aug 2020 20:35:07
	System	13 Aug 2020 20:35:07

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-13T16:35:02', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'c8a85787-5f98-484b-8b34-cccefa3a4b3a'	System	13 Aug 2020 20:35:07
User entered 'No (N)'	System	13 Aug 2020 20:35:07

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-13T16:35:04', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'c8a85787-5f98-484b-8b34-cccefa3a4b3a' User entered '13 Aug 2020 16:35'	System	13 Aug 2020 20:35:07
	System	13 Aug 2020 20:35:07

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered 'Day 5'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-14T15:14:37', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'bb78b3a6-631c-4619-8457-58fc6f3b4363' User entered 'None (0)'	System	14 Aug 2020 19:18:29
	System	14 Aug 2020 19:18:29

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-14T15:15:38', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'bb78b3a6-631c-4619-8457-58fc6f3b4363' User entered 'None (0)'	System	14 Aug 2020 19:18:29
	System	14 Aug 2020 19:18:29

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-14T15:15:40', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'bb78b3a6-631c-4619-8457-58fc6f3b4363' User entered 'None (0)'	System	14 Aug 2020 19:18:29
	System	14 Aug 2020 19:18:29

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-14T15:16:32', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'bb78b3a6-631c-4619-8457-58fc6f3b4363' User entered 'None (0)'	System	14 Aug 2020 19:18:29
	System	14 Aug 2020 19:18:29

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-14T15:16:34', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'bb78b3a6-631c-4619-8457-58fc6f3b4363' User entered 'None (0)'	System	14 Aug 2020 19:18:29
	System	14 Aug 2020 19:18:29

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-14T15:17:49', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'bb78b3a6-631c-4619-8457-58fc6f3b4363' User entered 'None (0)'	System	14 Aug 2020 19:18:29
	System	14 Aug 2020 19:18:29

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-14T15:18:24', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'bb78b3a6-631c-4619-8457-58fc6f3b4363' User entered 'No (N)'	System	14 Aug 2020 19:18:29
	System	14 Aug 2020 19:18:29

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-14T15:18:27', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'bb78b3a6-631c-4619-8457-58fc6f3b4363' User entered '14 Aug 2020 15:18'	System	14 Aug 2020 19:18:29
	System	14 Aug 2020 19:18:29

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered 'Day 6'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-15T15:24:49', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '4db76cfb-549e-42aa-a222-e171c38b8d91' User entered 'None (0)'	System	15 Aug 2020 19:25:04
	System	15 Aug 2020 19:25:04

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-15T15:24:50', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '4db76cfb-549e-42aa-a222-e171c38b8d91' User entered 'None (0)'	System	15 Aug 2020 19:25:04
	System	15 Aug 2020 19:25:04

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-15T15:24:51', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '4db76cfb-549e-42aa-a222-e171c38b8d91' User entered 'None (0)'	System	15 Aug 2020 19:25:04
	System	15 Aug 2020 19:25:04

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-15T15:24:53', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '4db76cfb-549e-42aa-a222-e171c38b8d91' User entered 'None (0)'	System	15 Aug 2020 19:25:04
	System	15 Aug 2020 19:25:04

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-15T15:24:55', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '4db76cfb-549e-42aa-a222-e171c38b8d91' User entered 'None (0)'	System	15 Aug 2020 19:25:04
	System	15 Aug 2020 19:25:04

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-15T15:24:57', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '4db76cfb-549e-42aa-a222-e171c38b8d91' User entered 'None (0)'	System	15 Aug 2020 19:25:04
	System	15 Aug 2020 19:25:04

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-15T15:24:59', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '4db76cfb-549e-42aa-a222-e171c38b8d91' User entered 'No (N)'	System	15 Aug 2020 19:25:04
	System	15 Aug 2020 19:25:04

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-15T15:25:01', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '4db76cfb-549e-42aa-a222-e171c38b8d91' User entered '15 Aug 2020 15:25'	System	15 Aug 2020 19:25:04
	System	15 Aug 2020 19:25:04

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered 'Day 7'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-16T17:29:52', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '362927c1-08d0-4530-aa70-8d2f633d54de' User entered 'None (0)'	System	16 Aug 2020 21:30:07
	System	16 Aug 2020 21:30:07

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-16T17:29:54', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '362927c1-08d0-4530-aa70-8d2f633d54de' User entered 'None (0)'	System	16 Aug 2020 21:30:07
	System	16 Aug 2020 21:30:07

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-16T17:29:56', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '362927c1-08d0-4530-aa70-8d2f633d54de' User entered 'None (0)'	System	16 Aug 2020 21:30:07
	System	16 Aug 2020 21:30:07

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-16T17:29:58', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '362927c1-08d0-4530-aa70-8d2f633d54de' User entered 'None (0)'	System	16 Aug 2020 21:30:07
	System	16 Aug 2020 21:30:07

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-16T17:29:59', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '362927c1-08d0-4530-aa70-8d2f633d54de' User entered 'None (0)'	System	16 Aug 2020 21:30:07
	System	16 Aug 2020 21:30:07

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-16T17:30:00', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '362927c1-08d0-4530-aa70-8d2f633d54de' User entered 'None (0)'	System	16 Aug 2020 21:30:07
	System	16 Aug 2020 21:30:07

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-16T17:30:02', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '362927c1-08d0-4530-aa70-8d2f633d54de' User entered 'No (N)'	System	16 Aug 2020 21:30:07
	System	16 Aug 2020 21:30:07

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-08-16T17:30:04', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '362927c1-08d0-4530-aa70-8d2f633d54de' User entered '16 Aug 2020 17:30'	System	16 Aug 2020 21:30:07
	System	16 Aug 2020 21:30:07

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 20:57:28

US3432081

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 20:57:28

US3432081

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Xhoi Mitre (b) (4)	20 Aug 2020 19:49:34

US3432081

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '17 Aug 2020'	Xhoi Mitre (b) (4)	20 Aug 2020 19:49:34

US3432081

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Contact Made (CONTACT MADE)'	Xhoi Mitre (b) (4)	20 Aug 2020 19:49:34

US3432081

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	Xhoi Mitre (b) (4)	20 Aug 2020 19:49:34

US3432081

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	24 Aug 2020 16:23:44

US3432081

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'I'	System	24 Aug 2020 16:23:44

US3432081

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	24 Aug 2020 20:41:22

US3432081

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '24 Aug 2020'	Phoebe Cunningham (b) (4)	24 Aug 2020 20:41:22

US3432081

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	24 Aug 2020 20:41:22

US3432081

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	Phoebe Cunningham (b) (4)	24 Aug 2020 20:41:22

US3432081

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	24 Aug 2020 20:41:26

US3432081

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'I'	System	24 Aug 2020 20:41:26

US3432081

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	31 Aug 2020 20:45:34

US3432081

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '31 Aug 2020'	Phoebe Cunningham (b) (4)	31 Aug 2020 20:45:34

US3432081

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	31 Aug 2020 20:45:34

US3432081

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	Phoebe Cunningham (b) (4)	31 Aug 2020 20:45:34

US3432081

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	31 Aug 2020 20:45:39

US3432081

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'I'	System	31 Aug 2020 20:45:39

US3432081

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	08 Sep 2020 22:05:14

US3432081

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:17

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '8 Sep 2020'	Jun Bai Park Chang (b) (4)	08 Sep 2020 22:05:14

US3432081

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Clinic (Clinic)'	Jun Bai Park Chang (b) (4)	08 Sep 2020 22:05:14

US3432081

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'VISIT2'	System	08 Sep 2020 22:05:14

US3432081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User accepted default value 'Pre-Dose (PREDOSE)'	Jun Bai Park Chang (b) (4)	08 Sep 2020 23:41:57

US3432081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:17

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	08 Sep 2020 23:41:57

US3432081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '8 Sep 2020'	Jun Bai Park Chang (b) (4)	08 Sep 2020 23:41:57

US3432081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '16:17'	Jun Bai Park Chang (b) (4)	08 Sep 2020 23:41:57

US3432081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered '8 Sep 2020 16:17'	System	08 Sep 2020 23:41:57

US3432081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '36.9' C	Jun Bai Park Chang (b) (4)	08 Sep 2020 23:41:57

US3432081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Oral (Oral)'	Jun Bai Park Chang (b) (4)	08 Sep 2020 23:41:57

US3432081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	Jun Bai Park Chang (b) (4)	08 Sep 2020 23:41:57

US3432081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '78'	Jun Bai Park Chang (b) (4)	08 Sep 2020 23:41:57

US3432081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'bpm'	System	08 Sep 2020 23:41:57

US3432081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '12'	Jun Bai Park Chang (b) (4)	08 Sep 2020 23:41:57

US3432081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'breaths/min'	System	08 Sep 2020 23:41:57

US3432081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '117'	Jun Bai Park Chang (b) (4)	08 Sep 2020 23:41:57

US3432081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'mmHg'	System	08 Sep 2020 23:41:57

US3432081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '062'	Jun Bai Park Chang (b) (4)	08 Sep 2020 23:41:57

US3432081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:31:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'mmHg'	System	08 Sep 2020 23:41:57

US3432081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User accepted default value 'Post-Dose (POSTDOSE)'	Jun Bai Park Chang (b) (4)	08 Sep 2020 23:41:57

US3432081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:17

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	08 Sep 2020 23:41:57

US3432081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '8 Sep 2020'	Jun Bai Park Chang (b) (4)	08 Sep 2020 23:41:57

US3432081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '18:29'	Jun Bai Park Chang (b) (4)	08 Sep 2020 23:41:57

US3432081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered '8 Sep 2020 18:29'	System	08 Sep 2020 23:41:57

US3432081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '36.7' C	Jun Bai Park Chang (b) (4)	08 Sep 2020 23:41:57

US3432081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Oral (Oral)'	Jun Bai Park Chang (b) (4)	08 Sep 2020 23:41:57

US3432081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	Jun Bai Park Chang (b) (4)	08 Sep 2020 23:41:57

US3432081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '51'	Jun Bai Park Chang (b) (4)	08 Sep 2020 23:41:57

US3432081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'bpm'	System	08 Sep 2020 23:41:57

US3432081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '14'	Jun Bai Park Chang (b) (4)	08 Sep 2020 23:41:57

US3432081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'breaths/min'	System	08 Sep 2020 23:41:57

US3432081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '108'	Jun Bai Park Chang (b) (4)	08 Sep 2020 23:41:57

US3432081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'mmHg'	System	08 Sep 2020 23:41:57

US3432081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '65'	Jun Bai Park Chang (b) (4)	08 Sep 2020 23:41:57

US3432081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:31:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'mmHg'	System	08 Sep 2020 23:41:57

US3432081

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	08 Sep 2020 22:10:04

US3432081

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '8 Sep 2020'	Jun Bai Park Chang (b) (4)	08 Sep 2020 22:10:04

US3432081

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:31:17

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	08 Sep 2020 22:09:53

US3432081

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:31:17

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '8 Sep 2020'	Jun Bai Park Chang (b) (4)	08 Sep 2020 22:09:53

US3432081

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:31:17

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Urine (URINE)'	Jun Bai Park Chang (b) (4)	08 Sep 2020 22:09:53

US3432081

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:31:17

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Negative (NEGATIVE)'	Jun Bai Park Chang (b) (4)	08 Sep 2020 22:09:53

US3432081

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:31:17

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	Jun Bai Park Chang (b) (4)	08 Sep 2020 22:09:53

US3432081

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:31:17

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	Jun Bai Park Chang (b) (4)	08 Sep 2020 22:09:53

US3432081

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:31:17

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	Jun Bai Park Chang (b) (4)	08 Sep 2020 22:09:53

US3432081

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered empty.	System	08 Sep 2020 22:09:53

US3432081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:17

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	08 Sep 2020 22:05:32

US3432081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:17

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	Jun Bai Park Chang (b) (4)	08 Sep 2020 22:05:32

US3432081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:17

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)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	Jun Bai Park Chang (b) (4)	08 Sep 2020 22:05:32

US3432081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:17

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 22:05:32

US3432081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:17

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '8 Sep 2020'	Jun Bai Park Chang (b) (4)	08 Sep 2020 22:05:32

US3432081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:17

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '17:59'	Jun Bai Park Chang (b) (4)	08 Sep 2020 22:05:32

US3432081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:17

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered '8 Sep 2020 17:59'	System	08 Sep 2020 22:05:32

US3432081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:17

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Left Arm (LEFT ARM)'	Jun Bai Park Chang (b) (4)	08 Sep 2020 22:05:32

US3432081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:17

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'ONCE'	System	08 Sep 2020 22:05:32

US3432081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:31:17

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 22:05:32

US3432081

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	08 Sep 2020 23:42:43

US3432081

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User closed query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 08SEP2020, however this date is presently recorded for Visit 2 Day 29. Please clarify if the Unscheduled sample collected on 08SEP2020 is actually for Visit 2 Day 29 and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:12:58
Query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 08SEP2020, however this date is presently recorded for Visit 2 Day 29. Please clarify if the Unscheduled sample collected on 08SEP2020 is actually for Visit 2 Day 29 and update as appropriate.' answered with 'Updated on PPD.' (Site from DM).	Jun Bai Park Chang (b) (4)	10 Nov 2020 14:44:41
User opened query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 08SEP2020, however this date is presently recorded for Visit 2 Day 29. Please clarify if the Unscheduled sample collected on 08SEP2020 is actually for Visit 2 Day 29 and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 19:23:03
User entered '8 Sep 2020'	Jun Bai Park Chang (b) (4)	08 Sep 2020 23:42:43

US3432081

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '16:55'	Jun Bai Park Chang (b) (4)	08 Sep 2020 23:42:43

US3432081

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered '8 Sep 2020 16:55'	System	08 Sep 2020 23:42:43

US3432081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:31:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 08SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 11:41:35
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 08SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'Updated on PPD.' (Site from DM).	Jun Bai Park Chang (b) (4)	10 Nov 2020 14:41:42
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 08SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 04:40:28
User entered '8 Sep 2020'	Jun Bai Park Chang (b) (4)	08 Sep 2020 23:42:56

US3432081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:31:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jun Bai Park Chang (b) (4)	08 Sep 2020 23:42:56

US3432081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:31:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	08 Sep 2020 23:42:56

US3432081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:31:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '17:05'	Jun Bai Park Chang (b) (4)	08 Sep 2020 23:42:56

US3432081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:31:17

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 08SEP2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in GCL. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' canceled (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 09:46:56
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 08SEP2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in GCL. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 07:55:12
User entered '8 Sep 2020 17:05'	System	08 Sep 2020 23:42:56

US3432081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:31:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jun Bai Park Chang (b) (4)	08 Sep 2020 23:42:56

US3432081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:31:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	Jun Bai Park Chang (b) (4)	08 Sep 2020 23:42:56

US3432081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:31:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	Jun Bai Park Chang (b) (4)	08 Sep 2020 23:42:56

US3432081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered empty.	System	08 Sep 2020 23:42:56

US3432081

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	08 Sep 2020 23:43:00

US3432081

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'I'	System	08 Sep 2020 23:43:00

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	08 Sep 2020 22:05:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-08T18:31:29', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'e5a90349-fd24-49c6-96e4-b97542430bcd' User entered 'Yes (Y)'	System	08 Sep 2020 22:31:42
	System	08 Sep 2020 22:31:42

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-08T18:31:34', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'e5a90349-fd24-49c6-96e4-b97542430bcd' User entered '98.0'	System	08 Sep 2020 22:31:42
	System	08 Sep 2020 22:31:42

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-08T18:31:37', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'e5a90349-fd24-49c6-96e4-b97542430bcd' User entered 'No (N)'	System	08 Sep 2020 22:31:42
	System	08 Sep 2020 22:31:42

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-08T18:31:40', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'e5a90349-fd24-49c6-96e4-b97542430bcd' User entered '08 Sep 2020 18:31'	System	08 Sep 2020 22:31:42
	System	08 Sep 2020 22:31:42

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '08 Sep 2020 18:19'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '08 Sep 2020 20:49'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	08 Sep 2020 22:05:32
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-08T21:44:11', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'ba057009-f3f3-4f61-9dfe-3bca81e0d455'	System	09 Sep 2020 01:44:21
User entered 'Yes (Y)'	System	09 Sep 2020 01:44:21

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-08T21:44:15', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'ba057009-f3f3-4f61-9dfe-3bca81e0d455'	System	09 Sep 2020 01:44:21
User entered '98.0'	System	09 Sep 2020 01:44:21

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-08T21:44:17', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'ba057009-f3f3-4f61-9dfe-3bca81e0d455'	System	09 Sep 2020 01:44:21
User entered 'No (N)'	System	09 Sep 2020 01:44:21

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-08T21:44:19', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'ba057009-f3f3-4f61-9dfe-3bca81e0d455'	System	09 Sep 2020 01:44:21
User entered '08 Sep 2020 21:44'	System	09 Sep 2020 01:44:21

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '08 Sep 2020 21:44'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	08 Sep 2020 22:05:32
User entered 'Day 2'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-09T12:05:45', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '800481c6-61d0-4c74-8e98-d0a056474b49'	System	09 Sep 2020 16:06:30
User entered 'Yes (Y)'	System	09 Sep 2020 16:06:30

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-09T12:05:49', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '800481c6-61d0-4c74-8e98-d0a056474b49' User entered '96.8'	System	09 Sep 2020 16:06:30
	System	09 Sep 2020 16:06:30

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-09T12:05:51', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '800481c6-61d0-4c74-8e98-d0a056474b49'	System	09 Sep 2020 16:06:30
User entered 'Yes (Y)'	System	09 Sep 2020 16:06:30

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Will record this on the next safety call.' (Site from System).	(b) (4), (b) (6)	15 Sep 2020 09:38:20
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Jun Bai Park Chang	14 Sep 2020 15:47:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-09T12:05:55', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '800481c6-61d0-4c74-8e98-d0a056474b49'	(b) (4)	
User entered '1'	System	09 Sep 2020 16:06:30

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:17

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-09T12:05:55', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '800481c6-61d0-4c74-8e98-d0a056474b49' User entered '0'	System	09 Sep 2020 16:06:30
	System	09 Sep 2020 16:06:30

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-09T12:06:02', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '800481c6-61d0-4c74-8e98-d0a056474b49'	System	09 Sep 2020 16:06:30
User entered '09 Sep 2020 12:06'	System	09 Sep 2020 16:06:30

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	08 Sep 2020 22:05:32
User entered 'Day 3'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-10T15:38:29', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '24422655-0366-45c5-8682-eeba8808cfc2'	System	10 Sep 2020 19:39:01
User entered 'Yes (Y)'	System	10 Sep 2020 19:39:01

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-10T15:38:41', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '24422655-0366-45c5-8682-eeba8808cfc2' User entered '96.6'	System	10 Sep 2020 19:39:01
	System	10 Sep 2020 19:39:01

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-10T15:38:43', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '24422655-0366-45c5-8682-eeba8808cfc2'	System	10 Sep 2020 19:39:01
User entered 'No (N)'	System	10 Sep 2020 19:39:01

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-10T15:38:59', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '24422655-0366-45c5-8682-eeba8808cfc2' User entered '10 Sep 2020 15:38'	System	10 Sep 2020 19:39:01
	System	10 Sep 2020 19:39:01

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	08 Sep 2020 22:05:32
User entered 'Day 4'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-11T14:41:31', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'd631098d-56f1-4837-b0f6-7a0c57f62366'	System	11 Sep 2020 18:41:39
User entered 'No (N)'	System	11 Sep 2020 18:41:39

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-11T14:41:33', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'd631098d-56f1-4837-b0f6-7a0c57f62366'	System	11 Sep 2020 18:41:39
User entered 'No (N)'	System	11 Sep 2020 18:41:39

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-11T14:41:35', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'd631098d-56f1-4837-b0f6-7a0c57f62366'	System	11 Sep 2020 18:41:39
User entered '11 Sep 2020 14:41'	System	11 Sep 2020 18:41:39

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	08 Sep 2020 22:05:32
User entered 'Day 5'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-12T16:57:08', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '59a68852-a6c3-4b41-a9f1-80a3a2d45d9d' User entered 'Yes (Y)'	System	12 Sep 2020 20:57:24
	System	12 Sep 2020 20:57:24

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-12T16:57:16', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '59a68852-a6c3-4b41-a9f1-80a3a2d45d9d' User entered '95.1'	System	12 Sep 2020 20:57:24
	System	12 Sep 2020 20:57:24

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-12T16:57:18', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '59a68852-a6c3-4b41-a9f1-80a3a2d45d9d'	System	12 Sep 2020 20:57:24
User entered 'No (N)'	System	12 Sep 2020 20:57:24

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-12T16:57:20', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '59a68852-a6c3-4b41-a9f1-80a3a2d45d9d' User entered '12 Sep 2020 16:57'	System	12 Sep 2020 20:57:24
	System	12 Sep 2020 20:57:24

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	08 Sep 2020 22:05:32
User entered 'Day 6'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-13T19:02:47', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '2c898eb6-37fe-4d5f-9ec4-8e52e5e0d876'	System	13 Sep 2020 23:03:00
User entered 'Yes (Y)'	System	13 Sep 2020 23:03:00

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-13T19:02:51', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '2c898eb6-37fe-4d5f-9ec4-8e52e5e0d876' User entered '96.1'	System	13 Sep 2020 23:03:00
	System	13 Sep 2020 23:03:00

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-13T19:02:55', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '2c898eb6-37fe-4d5f-9ec4-8e52e5e0d876'	System	13 Sep 2020 23:03:00
User entered 'No (N)'	System	13 Sep 2020 23:03:00

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-13T19:02:58', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '2c898eb6-37fe-4d5f-9ec4-8e52e5e0d876'	System	13 Sep 2020 23:03:00
User entered '13 Sep 2020 19:02'	System	13 Sep 2020 23:03:00

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	08 Sep 2020 22:05:32
User entered 'Day 7'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-14T21:35:52', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '17b9157d-d73b-449e-a320-0f435e08d238'	System	15 Sep 2020 01:36:26
User entered 'Yes (Y)'	System	15 Sep 2020 01:36:26

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-14T21:36:09', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '17b9157d-d73b-449e-a320-0f435e08d238' User entered '95.7'	System	15 Sep 2020 01:36:26
	System	15 Sep 2020 01:36:26

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-14T21:36:12', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '17b9157d-d73b-449e-a320-0f435e08d238' User entered 'No (N)'	System	15 Sep 2020 01:36:26
	System	15 Sep 2020 01:36:26

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-14T21:36:14', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '17b9157d-d73b-449e-a320-0f435e08d238'	System	15 Sep 2020 01:36:26
User entered '14 Sep 2020 21:36'	System	15 Sep 2020 01:36:26

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	08 Sep 2020 22:05:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-08T18:31:44', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '6d87b355-271b-4948-8e19-e43dfe141d26'	System	08 Sep 2020 22:31:57
User entered 'None (1)'	System	08 Sep 2020 22:31:57

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-08T18:31:47', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '6d87b355-271b-4948-8e19-e43dfe141d26' User entered 'No (N)'	System	08 Sep 2020 22:31:57
	System	08 Sep 2020 22:31:57

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-08T18:31:50', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '6d87b355-271b-4948-8e19-e43dfe141d26'	System	08 Sep 2020 22:31:57
User entered 'No (N)'	System	08 Sep 2020 22:31:57

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-08T18:31:52', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '6d87b355-271b-4948-8e19-e43dfe141d26'	System	08 Sep 2020 22:31:57
User entered 'None (1)'	System	08 Sep 2020 22:31:57

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-08T18:31:54', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '6d87b355-271b-4948-8e19-e43dfe141d26' User entered '08 Sep 2020 18:31'	System	08 Sep 2020 22:31:57
	System	08 Sep 2020 22:31:57

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '08 Sep 2020 18:19'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '08 Sep 2020 20:49'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	08 Sep 2020 22:05:32
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-08T21:44:27', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '24b70d38-e9ca-442c-a4c0-27c0caf9dac3'	System	09 Sep 2020 01:44:46
User entered 'Does not interfere with activity (2)'	System	09 Sep 2020 01:44:46

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-08T21:44:29', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '24b70d38-e9ca-442c-a4c0-27c0caf9dac3' User entered 'No (N)'	System	09 Sep 2020 01:44:46
	System	09 Sep 2020 01:44:46

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-08T21:44:39', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '24b70d38-e9ca-442c-a4c0-27c0caf9dac3' User entered 'No (N)'	System	09 Sep 2020 01:44:46
	System	09 Sep 2020 01:44:46

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-08T21:44:42', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '24b70d38-e9ca-442c-a4c0-27c0caf9dac3' User entered 'None (1)'	System	09 Sep 2020 01:44:46
	System	09 Sep 2020 01:44:46

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-08T21:44:45', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '24b70d38-e9ca-442c-a4c0-27c0caf9dac3' User entered '08 Sep 2020 21:44'	System	09 Sep 2020 01:44:46
	System	09 Sep 2020 01:44:46

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '08 Sep 2020 21:44'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	08 Sep 2020 22:05:32
User entered 'Day 2'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-09T12:06:08', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'a1a0d762-717c-48fc-b095-7cb9e65e6422'	System	09 Sep 2020 16:06:45
User entered 'Does not interfere with activity (2)'	System	09 Sep 2020 16:06:45

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-09T12:06:11', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'a1a0d762-717c-48fc-b095-7cb9e65e6422'	System	09 Sep 2020 16:06:45
User entered 'No (N)'	System	09 Sep 2020 16:06:45

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-09T12:06:20', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'a1a0d762-717c-48fc-b095-7cb9e65e6422'	System	09 Sep 2020 16:06:45
User entered 'No (N)'	System	09 Sep 2020 16:06:45

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-09T12:06:23', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'a1a0d762-717c-48fc-b095-7cb9e65e6422'	System	09 Sep 2020 16:06:45
User entered 'Does not interfere with activity (2)'	System	09 Sep 2020 16:06:45

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-09T12:06:26', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'a1a0d762-717c-48fc-b095-7cb9e65e6422' User entered '09 Sep 2020 12:06'	System	09 Sep 2020 16:06:45
	System	09 Sep 2020 16:06:45

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	08 Sep 2020 22:05:32
User entered 'Day 3'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-10T15:37:46', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'cd1699a7-49bb-4d8c-8d71-0d979f1afa49'	System	10 Sep 2020 19:38:07
User entered 'Does not interfere with activity (2)'	System	10 Sep 2020 19:38:07

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-10T15:37:49', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'cd1699a7-49bb-4d8c-8d71-0d979f1afa49' User entered 'No (N)'	System	10 Sep 2020 19:38:07
	System	10 Sep 2020 19:38:07

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-10T15:37:56', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'cd1699a7-49bb-4d8c-8d71-0d979f1afa49'	System	10 Sep 2020 19:38:07
User entered 'No (N)'	System	10 Sep 2020 19:38:07

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-10T15:37:59', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'cd1699a7-49bb-4d8c-8d71-0d979f1afa49'	System	10 Sep 2020 19:38:07
User entered 'Does not interfere with activity (2)'	System	10 Sep 2020 19:38:07

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-10T15:38:02', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'cd1699a7-49bb-4d8c-8d71-0d979f1afa49' User entered '10 Sep 2020 15:38'	System	10 Sep 2020 19:38:07
	System	10 Sep 2020 19:38:07

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	08 Sep 2020 22:05:32
User entered 'Day 4'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-11T14:41:47', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '295781df-e98b-49f4-84ef-08b60b5c7c1d'	System	11 Sep 2020 18:42:05
User entered 'None (1)'	System	11 Sep 2020 18:42:05

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-11T14:41:56', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '295781df-e98b-49f4-84ef-08b60b5c7c1d' User entered 'No (N)'	System	11 Sep 2020 18:42:05
	System	11 Sep 2020 18:42:05

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-11T14:41:58', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '295781df-e98b-49f4-84ef-08b60b5c7c1d' User entered 'No (N)'	System	11 Sep 2020 18:42:05
	System	11 Sep 2020 18:42:05

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-11T14:42:00', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '295781df-e98b-49f4-84ef-08b60b5c7c1d'	System	11 Sep 2020 18:42:05
User entered 'None (1)'	System	11 Sep 2020 18:42:05

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-11T14:42:03', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '295781df-e98b-49f4-84ef-08b60b5c7c1d' User entered '11 Sep 2020 14:42'	System	11 Sep 2020 18:42:05
	System	11 Sep 2020 18:42:05

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	08 Sep 2020 22:05:32
User entered 'Day 5'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-12T16:57:23', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '69bce743-fe0c-43fd-840c-bade103ea9e6' User entered 'None (1)'	System	12 Sep 2020 20:57:36
	System	12 Sep 2020 20:57:36

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-12T16:57:26', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '69bce743-fe0c-43fd-840c-bade103ea9e6'	System	12 Sep 2020 20:57:36
User entered 'No (N)'	System	12 Sep 2020 20:57:36

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-12T16:57:28', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '69bce743-fe0c-43fd-840c-bade103ea9e6'	System	12 Sep 2020 20:57:36
User entered 'No (N)'	System	12 Sep 2020 20:57:36

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-12T16:57:29', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '69bce743-fe0c-43fd-840c-bade103ea9e6' User entered 'None (1)'	System	12 Sep 2020 20:57:36
	System	12 Sep 2020 20:57:36

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-12T16:57:31', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '69bce743-fe0c-43fd-840c-bade103ea9e6' User entered '12 Sep 2020 16:57'	System	12 Sep 2020 20:57:36
	System	12 Sep 2020 20:57:36

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	08 Sep 2020 22:05:32
User entered 'Day 6'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-13T19:03:01', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'c71d3ea1-371e-4a45-8416-9c859cd865f5' User entered 'None (1)'	System	13 Sep 2020 23:03:13
	System	13 Sep 2020 23:03:13

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-13T19:03:03', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'c71d3ea1-371e-4a45-8416-9c859cd865f5' User entered 'No (N)'	System	13 Sep 2020 23:03:13
	System	13 Sep 2020 23:03:13

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-13T19:03:05', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'c71d3ea1-371e-4a45-8416-9c859cd865f5' User entered 'No (N)'	System	13 Sep 2020 23:03:13
	System	13 Sep 2020 23:03:13

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-13T19:03:06', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'c71d3ea1-371e-4a45-8416-9c859cd865f5' User entered 'None (1)'	System	13 Sep 2020 23:03:13
	System	13 Sep 2020 23:03:13

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-13T19:03:08', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'c71d3ea1-371e-4a45-8416-9c859cd865f5' User entered '13 Sep 2020 19:03'	System	13 Sep 2020 23:03:13
	System	13 Sep 2020 23:03:13

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	08 Sep 2020 22:05:32
User entered 'Day 7'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-14T21:35:26', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '1e94db4e-0416-4cd4-a818-3ad3dc2dd2c9' User entered 'None (1)'	System	15 Sep 2020 01:35:37
	System	15 Sep 2020 01:35:37

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-14T21:35:28', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '1e94db4e-0416-4cd4-a818-3ad3dc2dd2c9' User entered 'No (N)'	System	15 Sep 2020 01:35:37
	System	15 Sep 2020 01:35:37

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-14T21:35:29', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '1e94db4e-0416-4cd4-a818-3ad3dc2dd2c9' User entered 'No (N)'	System	15 Sep 2020 01:35:37
	System	15 Sep 2020 01:35:37

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-14T21:35:31', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '1e94db4e-0416-4cd4-a818-3ad3dc2dd2c9' User entered 'None (1)'	System	15 Sep 2020 01:35:37
	System	15 Sep 2020 01:35:37

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-14T21:35:34', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '1e94db4e-0416-4cd4-a818-3ad3dc2dd2c9' User entered '14 Sep 2020 21:35'	System	15 Sep 2020 01:35:37
	System	15 Sep 2020 01:35:37

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	08 Sep 2020 22:05:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-08T18:31:57', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '28919bf6-77cb-4f7c-9f13-e43197db708c' User entered 'None (0)'	System	08 Sep 2020 22:32:16
	System	08 Sep 2020 22:32:16

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-08T18:31:59', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '28919bf6-77cb-4f7c-9f13-e43197db708c' User entered 'None (0)'	System	08 Sep 2020 22:32:16
	System	08 Sep 2020 22:32:16

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-08T18:32:01', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '28919bf6-77cb-4f7c-9f13-e43197db708c' User entered 'None (0)'	System	08 Sep 2020 22:32:16
	System	08 Sep 2020 22:32:16

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-08T18:32:02', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '28919bf6-77cb-4f7c-9f13-e43197db708c' User entered 'None (0)'	System	08 Sep 2020 22:32:16
	System	08 Sep 2020 22:32:16

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-08T18:32:04', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '28919bf6-77cb-4f7c-9f13-e43197db708c' User entered 'None (0)'	System	08 Sep 2020 22:32:16
	System	08 Sep 2020 22:32:16

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-08T18:32:06', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '28919bf6-77cb-4f7c-9f13-e43197db708c' User entered 'None (0)'	System	08 Sep 2020 22:32:16
	System	08 Sep 2020 22:32:16

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-08T18:32:10', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '28919bf6-77cb-4f7c-9f13-e43197db708c' User entered 'No (N)'	System	08 Sep 2020 22:32:16
	System	08 Sep 2020 22:32:16

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-08T18:32:13', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '28919bf6-77cb-4f7c-9f13-e43197db708c' User entered '08 Sep 2020 18:32'	System	08 Sep 2020 22:32:16
	System	08 Sep 2020 22:32:16

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '08 Sep 2020 18:19'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '08 Sep 2020 20:49'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	08 Sep 2020 22:05:32
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-08T21:44:48', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '0f2f8105-db2b-41b0-a3cd-79a621878f74' User entered 'None (0)'	System	09 Sep 2020 01:45:02
	System	09 Sep 2020 01:45:02

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-08T21:44:49', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '0f2f8105-db2b-41b0-a3cd-79a621878f74' User entered 'None (0)'	System	09 Sep 2020 01:45:02
	System	09 Sep 2020 01:45:02

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-08T21:44:51', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '0f2f8105-db2b-41b0-a3cd-79a621878f74' User entered 'None (0)'	System	09 Sep 2020 01:45:02
	System	09 Sep 2020 01:45:02

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-08T21:44:52', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '0f2f8105-db2b-41b0-a3cd-79a621878f74' User entered 'None (0)'	System	09 Sep 2020 01:45:02
	System	09 Sep 2020 01:45:02

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-08T21:44:54', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '0f2f8105-db2b-41b0-a3cd-79a621878f74' User entered 'None (0)'	System	09 Sep 2020 01:45:02
	System	09 Sep 2020 01:45:02

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-08T21:44:55', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '0f2f8105-db2b-41b0-a3cd-79a621878f74' User entered 'None (0)'	System	09 Sep 2020 01:45:02
	System	09 Sep 2020 01:45:02

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-08T21:44:57', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '0f2f8105-db2b-41b0-a3cd-79a621878f74' User entered 'No (N)'	System	09 Sep 2020 01:45:02
	System	09 Sep 2020 01:45:02

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-08T21:44:59', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '0f2f8105-db2b-41b0-a3cd-79a621878f74' User entered '08 Sep 2020 21:44'	System	09 Sep 2020 01:45:02
	System	09 Sep 2020 01:45:02

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '08 Sep 2020 21:44'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	08 Sep 2020 22:05:32
User entered 'Day 2'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-09T12:03:54', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '7b970b72-d5c7-46c1-bc22-28a5cc01170d'	System	09 Sep 2020 16:06:01
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	09 Sep 2020 16:06:01

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-09T12:03:59', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '7b970b72-d5c7-46c1-bc22-28a5cc01170d'	System	09 Sep 2020 16:06:01
User entered 'Some interference with activity (2)'	System	09 Sep 2020 16:06:01

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-09T12:04:31', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '7b970b72-d5c7-46c1-bc22-28a5cc01170d' User entered 'Some interference with activity (2)'	System	09 Sep 2020 16:06:01
	System	09 Sep 2020 16:06:01

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-09T12:04:37', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '7b970b72-d5c7-46c1-bc22-28a5cc01170d' User entered 'Some interference with activity (2)'	System	09 Sep 2020 16:06:01
	System	09 Sep 2020 16:06:01

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-09T12:04:46', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '7b970b72-d5c7-46c1-bc22-28a5cc01170d' User entered 'None (0)'	System	09 Sep 2020 16:06:01
	System	09 Sep 2020 16:06:01

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-09T12:05:04', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '7b970b72-d5c7-46c1-bc22-28a5cc01170d'	System	09 Sep 2020 16:06:01
User entered 'Some interference with activity not requiring medical attention (2)'	System	09 Sep 2020 16:06:01

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-09T12:05:08', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '7b970b72-d5c7-46c1-bc22-28a5cc01170d' User entered 'No (N)'	System	09 Sep 2020 16:06:01
	System	09 Sep 2020 16:06:01

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-09T12:05:11', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '7b970b72-d5c7-46c1-bc22-28a5cc01170d' User entered '09 Sep 2020 12:05'	System	09 Sep 2020 16:06:01
	System	09 Sep 2020 16:06:01

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	08 Sep 2020 22:05:32
User entered 'Day 3'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-10T15:38:07', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '64d9a777-6fcf-4688-b38a-3c48a7ba88b0'	System	10 Sep 2020 19:38:29
User entered 'No interference with activity (1)'	System	10 Sep 2020 19:38:29

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-10T15:38:09', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '64d9a777-6fcf-4688-b38a-3c48a7ba88b0'	System	10 Sep 2020 19:38:29
User entered 'No interference with activity (1)'	System	10 Sep 2020 19:38:29

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-10T15:38:13', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '64d9a777-6fcf-4688-b38a-3c48a7ba88b0'	System	10 Sep 2020 19:38:29
User entered 'Some interference with activity (2)'	System	10 Sep 2020 19:38:29

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-10T15:38:16', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '64d9a777-6fcf-4688-b38a-3c48a7ba88b0'	System	10 Sep 2020 19:38:29
User entered 'No interference with activity (1)'	System	10 Sep 2020 19:38:29

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-10T15:38:19', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '64d9a777-6fcf-4688-b38a-3c48a7ba88b0' User entered 'None (0)'	System	10 Sep 2020 19:38:29
	System	10 Sep 2020 19:38:29

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-10T15:38:21', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '64d9a777-6fcf-4688-b38a-3c48a7ba88b0' User entered 'None (0)'	System	10 Sep 2020 19:38:29
	System	10 Sep 2020 19:38:29

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-10T15:38:23', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '64d9a777-6fcf-4688-b38a-3c48a7ba88b0' User entered 'No (N)'	System	10 Sep 2020 19:38:29
	System	10 Sep 2020 19:38:29

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-10T15:38:25', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '64d9a777-6fcf-4688-b38a-3c48a7ba88b0' User entered '10 Sep 2020 15:38'	System	10 Sep 2020 19:38:29
	System	10 Sep 2020 19:38:29

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	08 Sep 2020 22:05:32
User entered 'Day 4'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-11T14:42:13', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '231c66a0-5678-428b-a1db-e6e5db41922e' User entered 'None (0)'	System	11 Sep 2020 18:42:41
	System	11 Sep 2020 18:42:41

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-11T14:42:16', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '231c66a0-5678-428b-a1db-e6e5db41922e' User entered 'None (0)'	System	11 Sep 2020 18:42:41
	System	11 Sep 2020 18:42:41

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-11T14:42:18', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '231c66a0-5678-428b-a1db-e6e5db41922e' User entered 'None (0)'	System	11 Sep 2020 18:42:41
	System	11 Sep 2020 18:42:41

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-11T14:42:20', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '231c66a0-5678-428b-a1db-e6e5db41922e' User entered 'None (0)'	System	11 Sep 2020 18:42:41
	System	11 Sep 2020 18:42:41

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-11T14:42:22', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '231c66a0-5678-428b-a1db-e6e5db41922e' User entered 'None (0)'	System	11 Sep 2020 18:42:41
	System	11 Sep 2020 18:42:41

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-11T14:42:24', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '231c66a0-5678-428b-a1db-e6e5db41922e' User entered 'None (0)'	System	11 Sep 2020 18:42:41
	System	11 Sep 2020 18:42:41

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-11T14:42:29', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '231c66a0-5678-428b-a1db-e6e5db41922e' User entered 'No (N)'	System	11 Sep 2020 18:42:41
	System	11 Sep 2020 18:42:41

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-11T14:42:36', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '231c66a0-5678-428b-a1db-e6e5db41922e' User entered '11 Sep 2020 14:42'	System	11 Sep 2020 18:42:41
	System	11 Sep 2020 18:42:41

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	08 Sep 2020 22:05:32
User entered 'Day 5'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-12T16:57:34', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '359111eb-6473-46d5-b5e3-5bfd82093616' User entered 'None (0)'	System	12 Sep 2020 20:57:45
	System	12 Sep 2020 20:57:45

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-12T16:57:35', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '359111eb-6473-46d5-b5e3-5bfd82093616' User entered 'None (0)'	System	12 Sep 2020 20:57:45
	System	12 Sep 2020 20:57:45

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-12T16:57:36', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '359111eb-6473-46d5-b5e3-5bfd82093616' User entered 'None (0)'	System	12 Sep 2020 20:57:45
	System	12 Sep 2020 20:57:45

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-12T16:57:37', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '359111eb-6473-46d5-b5e3-5bfd82093616' User entered 'None (0)'	System	12 Sep 2020 20:57:45
	System	12 Sep 2020 20:57:45

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-12T16:57:39', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '359111eb-6473-46d5-b5e3-5bfd82093616' User entered 'None (0)'	System	12 Sep 2020 20:57:45
	System	12 Sep 2020 20:57:45

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-12T16:57:40', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '359111eb-6473-46d5-b5e3-5bfd82093616' User entered 'None (0)'	System	12 Sep 2020 20:57:45
	System	12 Sep 2020 20:57:45

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-12T16:57:42', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '359111eb-6473-46d5-b5e3-5bfd82093616' User entered 'No (N)'	System	12 Sep 2020 20:57:45
	System	12 Sep 2020 20:57:45

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-12T16:57:43', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '359111eb-6473-46d5-b5e3-5bfd82093616' User entered '12 Sep 2020 16:57'	System	12 Sep 2020 20:57:45
	System	12 Sep 2020 20:57:45

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	08 Sep 2020 22:05:32
User entered 'Day 6'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-13T19:03:10', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '0bc26c6e-0e2e-48fd-9417-7223f1076308' User entered 'None (0)'	System	13 Sep 2020 23:03:47
	System	13 Sep 2020 23:03:47

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-13T19:03:11', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '0bc26c6e-0e2e-48fd-9417-7223f1076308' User entered 'None (0)'	System	13 Sep 2020 23:03:47
	System	13 Sep 2020 23:03:47

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-13T19:03:12', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '0bc26c6e-0e2e-48fd-9417-7223f1076308' User entered 'None (0)'	System	13 Sep 2020 23:03:47
	System	13 Sep 2020 23:03:47

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-13T19:03:15', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '0bc26c6e-0e2e-48fd-9417-7223f1076308' User entered 'None (0)'	System	13 Sep 2020 23:03:47
	System	13 Sep 2020 23:03:47

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-13T19:03:19', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '0bc26c6e-0e2e-48fd-9417-7223f1076308' User entered 'None (0)'	System	13 Sep 2020 23:03:47
	System	13 Sep 2020 23:03:47

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-13T19:03:37', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '0bc26c6e-0e2e-48fd-9417-7223f1076308' User entered 'None (0)'	System	13 Sep 2020 23:03:47
	System	13 Sep 2020 23:03:47

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-13T19:03:39', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '0bc26c6e-0e2e-48fd-9417-7223f1076308' User entered 'No (N)'	System	13 Sep 2020 23:03:47
	System	13 Sep 2020 23:03:47

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-13T19:03:45', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '0bc26c6e-0e2e-48fd-9417-7223f1076308' User entered '13 Sep 2020 19:03'	System	13 Sep 2020 23:03:47
	System	13 Sep 2020 23:03:47

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	08 Sep 2020 22:05:32
User entered 'Day 7'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:17

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-14T21:35:37', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'c1f378eb-9d2f-4403-aa4d-db631b9d31bd' User entered 'None (0)'	System	15 Sep 2020 01:35:49
	System	15 Sep 2020 01:35:49

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:17

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-14T21:35:38', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'c1f378eb-9d2f-4403-aa4d-db631b9d31bd' User entered 'None (0)'	System	15 Sep 2020 01:35:49
	System	15 Sep 2020 01:35:49

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:17

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-14T21:35:39', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'c1f378eb-9d2f-4403-aa4d-db631b9d31bd' User entered 'None (0)'	System	15 Sep 2020 01:35:49
	System	15 Sep 2020 01:35:49

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:17

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-14T21:35:41', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'c1f378eb-9d2f-4403-aa4d-db631b9d31bd' User entered 'None (0)'	System	15 Sep 2020 01:35:49
	System	15 Sep 2020 01:35:49

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:17

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-14T21:35:42', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'c1f378eb-9d2f-4403-aa4d-db631b9d31bd' User entered 'None (0)'	System	15 Sep 2020 01:35:49
	System	15 Sep 2020 01:35:49

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:17

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-14T21:35:43', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'c1f378eb-9d2f-4403-aa4d-db631b9d31bd' User entered 'None (0)'	System	15 Sep 2020 01:35:49
	System	15 Sep 2020 01:35:49

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:17

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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-14T21:35:45', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'c1f378eb-9d2f-4403-aa4d-db631b9d31bd' User entered 'No (N)'	System	15 Sep 2020 01:35:49
	System	15 Sep 2020 01:35:49

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-09-14T21:35:47', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'c1f378eb-9d2f-4403-aa4d-db631b9d31bd' User entered '14 Sep 2020 21:35'	System	15 Sep 2020 01:35:49
	System	15 Sep 2020 01:35:49

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 22:05:32

US3432081

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:31:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 22:05:32

US3432081

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Sep 2020 18:45:11

US3432081

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '15 Sep 2020'	(b) (4), (b) (6)	15 Sep 2020 18:45:11

US3432081

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	15 Sep 2020 18:45:11

US3432081

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 18:45:11

US3432081

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 18:22:33

US3432081

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'I'	System	22 Sep 2020 18:22:33

US3432081

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 18:26:38

US3432081

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '22 Sep 2020'	(b) (4), (b) (6)	22 Sep 2020 18:26:38

US3432081

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Sep 2020 18:26:38

US3432081

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 18:26:38

US3432081

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 16:03:15

US3432081

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'I'	System	29 Sep 2020 16:03:15

US3432081

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 16:03:31

US3432081

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '29 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 16:03:31

US3432081

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	29 Sep 2020 16:03:31

US3432081

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 16:03:31

US3432081

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 16:03:36

US3432081

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'I'	System	29 Sep 2020 16:03:36

US3432081

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:15:40

US3432081

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 20:15:40

US3432081

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	13 Oct 2020 20:15:40

US3432081

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'VISIT3'	System	13 Oct 2020 20:15:40

US3432081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:16:26

US3432081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 20:16:26

US3432081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '14:29'	(b) (4), (b) (6)	13 Oct 2020 20:16:26

US3432081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered '13 Oct 2020 14:29'	System	13 Oct 2020 20:16:26

US3432081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '036.4' C	(b) (4), (b) (6)	13 Oct 2020 20:16:26

US3432081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Oral (Oral)'	(b) (4), (b) (6)	13 Oct 2020 20:16:26

US3432081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 20:16:26

US3432081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '052'	(b) (4), (b) (6)	13 Oct 2020 20:16:26

US3432081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'bpm'	System	13 Oct 2020 20:16:26

US3432081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '014'	(b) (4), (b) (6)	13 Oct 2020 20:16:26

US3432081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'breaths/min'	System	13 Oct 2020 20:16:26

US3432081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '116'	(b) (4), (b) (6)	13 Oct 2020 20:16:26

US3432081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'mmHg'	System	13 Oct 2020 20:16:26

US3432081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '075'	(b) (4), (b) (6)	13 Oct 2020 20:16:26

US3432081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'mmHg'	System	13 Oct 2020 20:16:26

US3432081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39

US3432081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39

US3432081

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:16:35

US3432081

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 20:16:35

US3432081

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:16:53

US3432081

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 20:16:53

US3432081

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '14:49'	(b) (4), (b) (6)	13 Oct 2020 20:16:53

US3432081

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered '13 Oct 2020 14:49'	System	13 Oct 2020 20:16:53

US3432081

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:16:57

US3432081

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'I'	System	13 Oct 2020 20:16:57

US3432081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered 'Day 64'	System	10 Aug 2020 20:57:28

US3432081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-10-10T11:28:04', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '78094c69-1310-43b2-8e27-fbaf9e6c7e6a'	System	10 Oct 2020 15:28:10
User entered 'No (N)'	System	10 Oct 2020 15:28:10

US3432081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

Have you been exposed to someone with 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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-10-10T11:27:58', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '78094c69-1310-43b2-8e27-fbaf9e6c7e6a'	System	10 Oct 2020 15:28:10
User entered 'No (N)'	System	10 Oct 2020 15:28:10

US3432081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-10-10T11:28:07', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '78094c69-1310-43b2-8e27-fbaf9e6c7e6a' User entered '10 Oct 2020 11:28:07'	System	10 Oct 2020 15:28:10
	System	10 Oct 2020 15:28:10

US3432081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered '10 Oct 2020 00:01'	System	10 Aug 2020 20:57:28

US3432081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered '14 Oct 2020 23:59'	System	10 Aug 2020 20:57:28

US3432081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered 'Day 71'	System	10 Aug 2020 20:57:28

US3432081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-10-17T10:36:07', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'cb1977a2-6556-4f49-8167-d0fdbac1af85'	System	17 Oct 2020 14:36:21
User entered 'No (N)'	System	17 Oct 2020 14:36:21

US3432081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

Have you been exposed to someone with 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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-10-17T10:36:10', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'cb1977a2-6556-4f49-8167-d0fdbac1af85'	System	17 Oct 2020 14:36:21
User entered 'No (N)'	System	17 Oct 2020 14:36:21

US3432081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-10-17T10:36:18', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'cb1977a2-6556-4f49-8167-d0fdbac1af85' User entered '17 Oct 2020 10:36:18'	System	17 Oct 2020 14:36:21
	System	17 Oct 2020 14:36:21

US3432081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered '17 Oct 2020 00:01'	System	10 Aug 2020 20:57:28

US3432081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered '21 Oct 2020 23:59'	System	10 Aug 2020 20:57:28

US3432081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered 'Day 78'	System	10 Aug 2020 20:57:28

US3432081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-10-24T09:09:38', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '30865e95-f951-4ce7-8a51-bfdc252417c1' User entered 'No (N)'	System	24 Oct 2020 13:09:45
	System	24 Oct 2020 13:09:45

US3432081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

Have you been exposed to someone with 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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-10-24T09:09:41', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '30865e95-f951-4ce7-8a51-bfdc252417c1' User entered 'No (N)'	System	24 Oct 2020 13:09:45
	System	24 Oct 2020 13:09:45

US3432081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-10-24T09:09:43', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '30865e95-f951-4ce7-8a51-bfdc252417c1' User entered '24 Oct 2020 09:09:43'	System	24 Oct 2020 13:09:45
	System	24 Oct 2020 13:09:45

US3432081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered '24 Oct 2020 00:01'	System	10 Aug 2020 20:57:28

US3432081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered '28 Oct 2020 23:59'	System	10 Aug 2020 20:57:28

US3432081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered 'Day 92'	System	10 Aug 2020 20:57:28

US3432081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-11-07T09:58:40', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '587dc06e-36b7-47ab-92e6-d9f67b78c5bb' User entered 'No (N)'	System	07 Nov 2020 14:58:50
	System	07 Nov 2020 14:58:50

US3432081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

Have you been exposed to someone with 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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-11-07T09:58:45', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '587dc06e-36b7-47ab-92e6-d9f67b78c5bb'	System	07 Nov 2020 14:58:50
User entered 'No (N)'	System	07 Nov 2020 14:58:50

US3432081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-11-07T09:58:47', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '587dc06e-36b7-47ab-92e6-d9f67b78c5bb' User entered '07 Nov 2020 09:58:47'	System	07 Nov 2020 14:58:50
	System	07 Nov 2020 14:58:50

US3432081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered '07 Nov 2020 00:01'	System	10 Aug 2020 20:57:28

US3432081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered '11 Nov 2020 23:59'	System	10 Aug 2020 20:57:28

US3432081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered 'Day 99'	System	10 Aug 2020 20:57:28

US3432081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-11-14T08:59:34', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'd3195289-2421-4544-b193-c147c30cbccc' User entered 'No (N)'	System	14 Nov 2020 13:59:45
	System	14 Nov 2020 13:59:45

US3432081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

Have you been exposed to someone with 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 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-11-14T08:59:40', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'd3195289-2421-4544-b193-c147c30cbccc'	System	14 Nov 2020 13:59:45
User entered 'No (N)'	System	14 Nov 2020 13:59:45

US3432081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-11-14T08:59:42', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'd3195289-2421-4544-b193-c147c30cbccc' User entered '14 Nov 2020 08:59:42'	System	14 Nov 2020 13:59:45
	System	14 Nov 2020 13:59:45

US3432081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered '14 Nov 2020 00:01'	System	10 Aug 2020 20:57:28

US3432081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 18:18:18
Data entry locked.	System	10 Aug 2020 20:57:28
User entered '18 Nov 2020 23:59'	System	10 Aug 2020 20:57:28

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[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 (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-11-21T00:14:44', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '78832aff-56f6-4706-bf0e-5c5da101a4a4'	System	21 Nov 2020 05:15:00
User entered 'No (N)'	System	21 Nov 2020 05:15:00

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

Have you been exposed to someone with 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 (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-11-21T00:14:54', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '78832aff-56f6-4706-bf0e-5c5da101a4a4'	System	21 Nov 2020 05:15:00
User entered 'No (N)'	System	21 Nov 2020 05:15:00

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-11-21T00:14:57', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '78832aff-56f6-4706-bf0e-5c5da101a4a4'	System	21 Nov 2020 05:15:00
User entered '21 Nov 2020 00:14:57'	System	21 Nov 2020 05:15:00

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[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 (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-11-25T09:24:31', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'aff846d9-ceb1-4125-8f9e-8e3256ee32af' User entered 'No (N)'	System	25 Nov 2020 14:24:39

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

Have you been exposed to someone with 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 (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-11-25T09:24:33', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'aff846d9-ceb1-4125-8f9e-8e3256ee32af' User entered 'No (N)'	System	25 Nov 2020 14:24:39

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-11-25T09:24:36', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'aff846d9-ceb1-4125-8f9e-8e3256ee32af' User entered '25 Nov 2020 09:24:36'	System	25 Nov 2020 14:24:39

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[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 (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-12-02T11:08:08', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '7e1a052f-b086-4d38-b598-166dd58e3aa3' User entered 'No (N)'	System	02 Dec 2020 16:08:15
	System	02 Dec 2020 16:08:15

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

Have you been exposed to someone with 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 (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-12-02T11:08:10', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '7e1a052f-b086-4d38-b598-166dd58e3aa3'	System	02 Dec 2020 16:08:15
User entered 'No (N)'	System	02 Dec 2020 16:08:15

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-12-02T11:08:12', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '7e1a052f-b086-4d38-b598-166dd58e3aa3' User entered '02 Dec 2020 11:08:12'	System	02 Dec 2020 16:08:15
	System	02 Dec 2020 16:08:15

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[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 (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-12-09T10:10:38', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'a9d74a6c-b498-4cda-9366-c6127d413cab' User entered 'No (N)'	System	09 Dec 2020 15:10:46
	System	09 Dec 2020 15:10:46

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

Have you been exposed to someone with 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 (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-12-09T10:10:40', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'a9d74a6c-b498-4cda-9366-c6127d413cab' User entered 'No (N)'	System	09 Dec 2020 15:10:46
	System	09 Dec 2020 15:10:46

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-12-09T10:10:43', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'a9d74a6c-b498-4cda-9366-c6127d413cab' User entered '09 Dec 2020 10:10:43'	System	09 Dec 2020 15:10:46
	System	09 Dec 2020 15:10:46

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[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 (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-12-16T09:24:42', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'c466ecae-a91f-44cf-802d-fad5d4a2bffb'	System	16 Dec 2020 14:24:51
User entered 'No (N)'	System	16 Dec 2020 14:24:51

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Have you been exposed to someone with 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 (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-12-16T09:24:45', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'c466ecae-a91f-44cf-802d-fad5d4a2bffb'	System	16 Dec 2020 14:24:51
User entered 'No (N)'	System	16 Dec 2020 14:24:51

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-12-16T09:24:47', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'c466ecae-a91f-44cf-802d-fad5d4a2bffb' User entered '16 Dec 2020 09:24:47'	System	16 Dec 2020 14:24:51
	System	16 Dec 2020 14:24:51

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[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 (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-12-23T09:18:34', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '2abaff1c-f6b8-415a-98c1-979e4d47206f' User entered 'No (N)'	System	23 Dec 2020 14:19:11
	System	23 Dec 2020 14:19:11

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Have you been exposed to someone with 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 (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-12-23T09:19:03', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '2abaff1c-f6b8-415a-98c1-979e4d47206f' User entered 'No (N)'	System	23 Dec 2020 14:19:11

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-12-23T09:19:06', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '2abaff1c-f6b8-415a-98c1-979e4d47206f' User entered '23 Dec 2020 09:19:06'	System	23 Dec 2020 14:19:11
	System	23 Dec 2020 14:19:11

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[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 (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-12-30T07:35:25', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '104a2dbb-5882-4140-aa08-70dc19ab4daa' User entered 'No (N)'	System	30 Dec 2020 12:35:55
	System	30 Dec 2020 12:35:55

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Have you been exposed to someone with 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 (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-12-30T07:35:47', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '104a2dbb-5882-4140-aa08-70dc19ab4daa' User entered 'No (N)'	System	30 Dec 2020 12:35:55
	System	30 Dec 2020 12:35:55

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2020-12-30T07:35:51', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '104a2dbb-5882-4140-aa08-70dc19ab4daa' User entered '30 Dec 2020 07:35:51'	System	30 Dec 2020 12:35:55
	System	30 Dec 2020 12:35:55

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[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 (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2021-01-06T00:18:55', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '288406fc-a750-4126-9c87-659d5c1becea' User entered 'No (N)'	System	06 Jan 2021 05:19:04

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

Have you been exposed to someone with 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 (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2021-01-06T00:18:57', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '288406fc-a750-4126-9c87-659d5c1becea' User entered 'No (N)'	System	06 Jan 2021 05:19:04

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CA94F14E-FFD0-4994-AD7B-16EE0A872D46)', Time: '2021-01-06T00:19:00', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '288406fc-a750-4126-9c87-659d5c1becea' User entered '06 Jan 2021 00:19:00'	System	06 Jan 2021 05:19:04
	System	06 Jan 2021 05:19:04

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[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 (42A89868-F817-4903-A6C3-9DB60DFC17DA)', Time: '2021-01-23T09:22:28', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '6eb4d5dd-1c80-42e0-aa6c-b7468dd57c45'	System	23 Jan 2021 14:23:18
User entered 'Yes (Y)'	System	23 Jan 2021 14:23:18

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

Have you been exposed to someone with 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 (42A89868-F817-4903-A6C3-9DB60DFC17DA)', Time: '2021-01-23T09:22:34', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '6eb4d5dd-1c80-42e0-aa6c-b7468dd57c45'	System	23 Jan 2021 14:23:18
User entered 'No (N)'	System	23 Jan 2021 14:23:18

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[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 (42A89868-F817-4903-A6C3-9DB60DFC17DA)', Time: '2021-01-23T09:22:39', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '6eb4d5dd-1c80-42e0-aa6c-b7468dd57c45'	System	23 Jan 2021 14:23:18
User entered 'No (N)'	System	23 Jan 2021 14:23:18

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[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 (42A89868-F817-4903-A6C3-9DB60DFC17DA)', Time: '2021-01-23T09:22:51', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '6eb4d5dd-1c80-42e0-aa6c-b7468dd57c45'	System	23 Jan 2021 14:23:18
User entered 'Yes (Y)'	System	23 Jan 2021 14:23:18

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Please 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 (42A89868-F817-4903-A6C3-9DB60DFC17DA)', Time: '2021-01-23T09:23:04', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '6eb4d5dd-1c80-42e0-aa6c-b7468dd57c45'	System	23 Jan 2021 14:23:18
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	23 Jan 2021 14:23:18

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42A89868-F817-4903-A6C3-9DB60DFC17DA)', Time: '2021-01-23T09:23:08', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '6eb4d5dd-1c80-42e0-aa6c-b7468dd57c45' User entered '23 Jan 2021 09:23:08'	System	23 Jan 2021 14:23:18
	System	23 Jan 2021 14:23:18

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[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 (42A89868-F817-4903-A6C3-9DB60DFC17DA)', Time: '2021-01-27T07:00:38', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '7e416717-43ea-4a2a-9cee-7d53c06eeae9' User entered 'No (N)'	System	27 Jan 2021 12:00:48
	System	27 Jan 2021 12:00:48

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

Have you been exposed to someone with 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 (42A89868-F817-4903-A6C3-9DB60DFC17DA)', Time: '2021-01-27T07:00:41', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '7e416717-43ea-4a2a-9cee-7d53c06eeae9' User entered 'No (N)'	System	27 Jan 2021 12:00:48
	System	27 Jan 2021 12:00:48

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42A89868-F817-4903-A6C3-9DB60DFC17DA)', Time: '2021-01-27T07:00:44', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '7e416717-43ea-4a2a-9cee-7d53c06eeae9' User entered '27 Jan 2021 07:00:44'	System	27 Jan 2021 12:00:48
	System	27 Jan 2021 12:00:48

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[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 (42A89868-F817-4903-A6C3-9DB60DFC17DA)', Time: '2021-02-03T06:27:47', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '4e2cfad7-a954-455f-9f9b-b8d010f3c83e' User entered 'No (N)'	System	03 Feb 2021 11:27:56
	System	03 Feb 2021 11:27:56

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

Have you been exposed to someone with 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 (42A89868-F817-4903-A6C3-9DB60DFC17DA)', Time: '2021-02-03T06:27:51', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '4e2cfad7-a954-455f-9f9b-b8d010f3c83e' User entered 'No (N)'	System	03 Feb 2021 11:27:56
	System	03 Feb 2021 11:27:56

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (42A89868-F817-4903-A6C3-9DB60DFC17DA)', Time: '2021-02-03T06:27:54', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '4e2cfad7-a954-455f-9f9b-b8d010f3c83e' User entered '03 Feb 2021 06:27:54'	System	03 Feb 2021 11:27:56
	System	03 Feb 2021 11:27:56

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[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 (83BC0BC7-5D06-4D46-8069-6D3661B1C375)', Time: '2021-02-10T09:25:39', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '5e925c67-cc2c-4319-b6da-01fad41800e5' User entered 'No (N)'	System	10 Feb 2021 14:25:48
	System	10 Feb 2021 14:25:48

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Have you been exposed to someone with 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 (83BC0BC7-5D06-4D46-8069-6D3661B1C375)', Time: '2021-02-10T09:25:41', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '5e925c67-cc2c-4319-b6da-01fad41800e5' User entered 'No (N)'	System	10 Feb 2021 14:25:48

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83BC0BC7-5D06-4D46-8069-6D3661B1C375)', Time: '2021-02-10T09:25:44', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '5e925c67-cc2c-4319-b6da-01fad41800e5' User entered '10 Feb 2021 09:25:44'	System	10 Feb 2021 14:25:48
	System	10 Feb 2021 14:25:48

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[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 (83BC0BC7-5D06-4D46-8069-6D3661B1C375)', Time: '2021-02-17T09:55:10', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '4cb75168-5b95-4341-b3dc-1649b73199aa'	System	17 Feb 2021 14:55:16
User entered 'No (N)'	System	17 Feb 2021 14:55:16

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

Have you been exposed to someone with 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 (83BC0BC7-5D06-4D46-8069-6D3661B1C375)', Time: '2021-02-17T09:55:12', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '4cb75168-5b95-4341-b3dc-1649b73199aa'	System	17 Feb 2021 14:55:16
User entered 'No (N)'	System	17 Feb 2021 14:55:16

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83BC0BC7-5D06-4D46-8069-6D3661B1C375)', Time: '2021-02-17T09:55:14', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '4cb75168-5b95-4341-b3dc-1649b73199aa'	System	17 Feb 2021 14:55:16
User entered '17 Feb 2021 09:55:14'	System	17 Feb 2021 14:55:16

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[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 (83BC0BC7-5D06-4D46-8069-6D3661B1C375)', Time: '2021-02-24T10:24:15', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '34e0cadd-736f-49e6-98a8-9380d74f9d8f' User entered 'No (N)'	System	24 Feb 2021 15:24:22
	System	24 Feb 2021 15:24:22

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Have you been exposed to someone with 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 (83BC0BC7-5D06-4D46-8069-6D3661B1C375)', Time: '2021-02-24T10:24:17', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '34e0cadd-736f-49e6-98a8-9380d74f9d8f' User entered 'No (N)'	System	24 Feb 2021 15:24:22

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83BC0BC7-5D06-4D46-8069-6D3661B1C375)', Time: '2021-02-24T10:24:20', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '34e0cadd-736f-49e6-98a8-9380d74f9d8f' User entered '24 Feb 2021 10:24:20'	System	24 Feb 2021 15:24:22
	System	24 Feb 2021 15:24:22

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[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 (83BC0BC7-5D06-4D46-8069-6D3661B1C375)', Time: '2021-03-03T10:06:03-05:00', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'f4bfc7d3-507e-4cfa-ba7d-62a8d7c7cf31'	System	03 Mar 2021 15:06:11
User entered 'No (N)'	System	03 Mar 2021 15:06:11

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Have you been exposed to someone with 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 (83BC0BC7-5D06-4D46-8069-6D3661B1C375)', Time: '2021-03-03T10:06:05-05:00', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'f4bfc7d3-507e-4cfa-ba7d-62a8d7c7cf31'	System	03 Mar 2021 15:06:11
User entered 'No (N)'	System	03 Mar 2021 15:06:11

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83BC0BC7-5D06-4D46-8069-6D3661B1C375)', Time: '2021-03-03T10:06:07-05:00', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'f4bfc7d3-507e-4cfa-ba7d-62a8d7c7cf31'	System	03 Mar 2021 15:06:11
User entered '03 Mar 2021 10:06:07'	System	03 Mar 2021 15:06:11

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[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 (83BC0BC7-5D06-4D46-8069-6D3661B1C375)', Time: '2021-03-10T14:15:30-05:00', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '1f08afa9-6098-4c5e-bded-5b612b238ab2'	System	10 Mar 2021 19:15:53
User entered 'No (N)'	System	10 Mar 2021 19:15:53

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Have you been exposed to someone with 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 (83BC0BC7-5D06-4D46-8069-6D3661B1C375)', Time: '2021-03-10T14:15:31-05:00', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '1f08afa9-6098-4c5e-bded-5b612b238ab2'	System	10 Mar 2021 19:15:53
User entered 'No (N)'	System	10 Mar 2021 19:15:53

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83BC0BC7-5D06-4D46-8069-6D3661B1C375)', Time: '2021-03-10T14:15:33-05:00', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '1f08afa9-6098-4c5e-bded-5b612b238ab2'	System	10 Mar 2021 19:15:53
User entered '10 Mar 2021 14:15:33'	System	10 Mar 2021 19:15:53

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[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 (83BC0BC7-5D06-4D46-8069-6D3661B1C375)', Time: '2021-03-17T10:30:46-05:00', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'cce994fb-7563-4ab6-b849-a4be2deae04a' User entered 'No (N)'	System	17 Mar 2021 15:30:53
	System	17 Mar 2021 15:30:53

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

Have you been exposed to someone with 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 (83BC0BC7-5D06-4D46-8069-6D3661B1C375)', Time: '2021-03-17T10:30:48-05:00', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'cce994fb-7563-4ab6-b849-a4be2deae04a'	System	17 Mar 2021 15:30:53
User entered 'No (N)'	System	17 Mar 2021 15:30:53

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83BC0BC7-5D06-4D46-8069-6D3661B1C375)', Time: '2021-03-17T10:30:50-05:00', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'cce994fb-7563-4ab6-b849-a4be2deae04a'	System	17 Mar 2021 15:30:53
User entered '17 Mar 2021 10:30:50'	System	17 Mar 2021 15:30:53

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[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 (83BC0BC7-5D06-4D46-8069-6D3661B1C375)', Time: '2021-03-24T10:45:33-04:00', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '24e0a639-dcba-4c91-aa3c-3ba6ac305e49' User entered 'No (N)'	System	24 Mar 2021 14:45:41
	System	24 Mar 2021 14:45:41

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

Have you been exposed to someone with 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 (83BC0BC7-5D06-4D46-8069-6D3661B1C375)', Time: '2021-03-24T10:45:37-04:00', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '24e0a639-dcba-4c91-aa3c-3ba6ac305e49'	System	24 Mar 2021 14:45:41
User entered 'No (N)'	System	24 Mar 2021 14:45:41

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83BC0BC7-5D06-4D46-8069-6D3661B1C375)', Time: '2021-03-24T10:45:39-04:00', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '24e0a639-dcba-4c91-aa3c-3ba6ac305e49' User entered '24 Mar 2021 10:45:39'	System	24 Mar 2021 14:45:41
	System	24 Mar 2021 14:45:41

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[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 (83BC0BC7-5D06-4D46-8069-6D3661B1C375)', Time: '2021-03-31T06:29:09-04:00', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '76df8531-be9d-4f39-906a-6e406b18591d' User entered 'No (N)'	System	31 Mar 2021 10:29:16
	System	31 Mar 2021 10:29:16

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

Have you been exposed to someone with 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 (83BC0BC7-5D06-4D46-8069-6D3661B1C375)', Time: '2021-03-31T06:29:11-04:00', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '76df8531-be9d-4f39-906a-6e406b18591d'	System	31 Mar 2021 10:29:16
User entered 'No (N)'	System	31 Mar 2021 10:29:16

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83BC0BC7-5D06-4D46-8069-6D3661B1C375)', Time: '2021-03-31T06:29:13-04:00', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '76df8531-be9d-4f39-906a-6e406b18591d' User entered '31 Mar 2021 06:29:13'	System	31 Mar 2021 10:29:16
	System	31 Mar 2021 10:29:16

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[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 (83BC0BC7-5D06-4D46-8069-6D3661B1C375)', Time: '2021-04-07T13:33:49-04:00', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'd1bf4d9c-8f60-44d0-87be-e77df92b0d1a'	System	07 Apr 2021 17:33:56
User entered 'No (N)'	System	07 Apr 2021 17:33:56

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

Have you been exposed to someone with 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 (83BC0BC7-5D06-4D46-8069-6D3661B1C375)', Time: '2021-04-07T13:33:51-04:00', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'd1bf4d9c-8f60-44d0-87be-e77df92b0d1a'	System	07 Apr 2021 17:33:56
User entered 'No (N)'	System	07 Apr 2021 17:33:56

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83BC0BC7-5D06-4D46-8069-6D3661B1C375)', Time: '2021-04-07T13:33:52-04:00', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'd1bf4d9c-8f60-44d0-87be-e77df92b0d1a'	System	07 Apr 2021 17:33:56
User entered '07 Apr 2021 13:33:52'	System	07 Apr 2021 17:33:56

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[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 (83BC0BC7-5D06-4D46-8069-6D3661B1C375)', Time: '2021-04-14T07:08:40-04:00', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '986a70a7-c6a1-4d97-92a3-1b4c1d2dbf5d' User entered 'No (N)'	System	14 Apr 2021 13:35:55
	System	14 Apr 2021 13:35:55

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Have you been exposed to someone with 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 (83BC0BC7-5D06-4D46-8069-6D3661B1C375)', Time: '2021-04-14T07:08:41-04:00', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '986a70a7-c6a1-4d97-92a3-1b4c1d2dbf5d' User entered 'No (N)'	System	14 Apr 2021 13:35:55
	System	14 Apr 2021 13:35:55

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83BC0BC7-5D06-4D46-8069-6D3661B1C375)', Time: '2021-04-14T07:08:43-04:00', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '986a70a7-c6a1-4d97-92a3-1b4c1d2dbf5d' User entered '14 Apr 2021 07:08:43'	System	14 Apr 2021 13:35:55
	System	14 Apr 2021 13:35:55

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[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 (83BC0BC7-5D06-4D46-8069-6D3661B1C375)', Time: '2021-04-21T06:09:44-04:00', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '7d9b3ed7-1d8f-4e34-af3f-557a41c9d5dc'	System	21 Apr 2021 10:09:55
User entered 'No (N)'	System	21 Apr 2021 10:09:55

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Have you been exposed to someone with 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 (83BC0BC7-5D06-4D46-8069-6D3661B1C375)', Time: '2021-04-21T06:09:48-04:00', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '7d9b3ed7-1d8f-4e34-af3f-557a41c9d5dc'	System	21 Apr 2021 10:09:55
User entered 'No (N)'	System	21 Apr 2021 10:09:55

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83BC0BC7-5D06-4D46-8069-6D3661B1C375)', Time: '2021-04-21T06:09:52-04:00', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: '7d9b3ed7-1d8f-4e34-af3f-557a41c9d5dc' User entered '21 Apr 2021 06:09:52'	System	21 Apr 2021 10:09:55
	System	21 Apr 2021 10:09:55

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[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 (83BC0BC7-5D06-4D46-8069-6D3661B1C375)', Time: '2021-04-28T06:19:25-04:00', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'dfc467d8-c83a-476b-8ca7-e82e6d3b4f59'	System	29 Apr 2021 03:15:08
User entered 'No (N)'	System	29 Apr 2021 03:15:08

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Have you been exposed to someone with 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 (83BC0BC7-5D06-4D46-8069-6D3661B1C375)', Time: '2021-04-28T06:19:26-04:00', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'dfc467d8-c83a-476b-8ca7-e82e6d3b4f59'	System	29 Apr 2021 03:15:08
User entered 'No (N)'	System	29 Apr 2021 03:15:08

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83BC0BC7-5D06-4D46-8069-6D3661B1C375)', Time: '2021-04-28T06:19:28-04:00', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'dfc467d8-c83a-476b-8ca7-e82e6d3b4f59'	System	29 Apr 2021 03:15:08
User entered '28 Apr 2021 06:19:28'	System	29 Apr 2021 03:15:08

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 03:08:24

US3432081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:31:17

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:08:24
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 03:08:24

US3432081

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:31:17

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 03:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83BC0BC7-5D06-4D46-8069-6D3661B1C375)', Time: '2021-03-03T10:06:13-05:00', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'ae41fe62-24a8-4068-a632-0c9eeb38303b'	System	03 Mar 2021 15:06:19
User entered 'No (N)'	System	03 Mar 2021 15:06:19

US3432081

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:31:17

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 03:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (83BC0BC7-5D06-4D46-8069-6D3661B1C375)', Time: '2021-03-03T10:06:15-05:00', User OID: 'PatientReportedOutcome (US3432081)', ODM File OID: 'ae41fe62-24a8-4068-a632-0c9eeb38303b' User entered '03 Mar 2021 10:06:15'	System	03 Mar 2021 15:06:19
	System	03 Mar 2021 15:06:19

US3432081

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	02 Nov 2020 19:36:07

US3432081

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '2 Nov 2020'	Kathleen Garvey (b) (4)	02 Nov 2020 19:36:07

US3432081

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Contact Made (CONTACT MADE)'	Kathleen Garvey (b) (4)	02 Nov 2020 19:36:07

US3432081

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	Kathleen Garvey (b) (4)	02 Nov 2020 19:36:07

US3432081

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	02 Nov 2020 19:36:10

US3432081

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:56:39
User entered 'I'	System	02 Nov 2020 19:36:10

US3432081

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	04 Dec 2020 19:28:53

US3432081

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '4 Dec 2020'	Kathleen Garvey (b) (4)	04 Dec 2020 19:28:53

US3432081

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Contact Made (CONTACT MADE)'	Kathleen Garvey (b) (4)	04 Dec 2020 19:28:53

US3432081

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	Kathleen Garvey (b) (4)	04 Dec 2020 19:28:53

US3432081

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Kathleen Garvey (b) (4)	04 Dec 2020 19:28:57

US3432081

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User entered 'I'	System	04 Dec 2020 19:28:57

US3432081

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Jan 2021 21:02:56

US3432081

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '4 Jan 2021'	(b) (4), (b) (6)	04 Jan 2021 21:02:56

US3432081

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	04 Jan 2021 21:02:56

US3432081

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	(b) (4), (b) (6)	04 Jan 2021 21:02:56

US3432081

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Jan 2021 21:03:02

US3432081

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User entered 'I'	System	04 Jan 2021 21:03:02

US3432081

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Tenaizus Woods (b) (4)	03 Feb 2021 17:49:06

US3432081

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '3 Feb 2021'	Tenaizus Woods (b) (4)	03 Feb 2021 17:49:06

US3432081

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Contact Made (CONTACT MADE)'	Tenaizus Woods (b) (4)	03 Feb 2021 17:49:06

US3432081

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	Tenaizus Woods (b) (4)	03 Feb 2021 17:49:06

US3432081

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Tenaizus Woods (b) (4)	03 Feb 2021 17:49:13

US3432081

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User entered 'I'	System	03 Feb 2021 17:49:13

US3432081

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	30 Mar 2021 21:31:45

US3432081

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:17

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	31 Mar 2021 12:19:09
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'participant unable to come in within window' (Site from System).	Julia Klopfer (b) (4)	30 Mar 2021 21:31:58
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	30 Mar 2021 21:31:45
User entered '30 Mar 2021'	Julia Klopfer (b) (4)	30 Mar 2021 21:31:45

US3432081

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
User entered 'Clinic (Clinic)'	Julia Klopfer (b) (4)	30 Mar 2021 21:31:45

US3432081

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:31:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User entered 'VISIT4'	System	30 Mar 2021 21:31:45

US3432081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	30 Mar 2021 21:32:42

US3432081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
User entered '30 Mar 2021'	Julia Klopfer (b) (4)	30 Mar 2021 21:32:42

US3432081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
User entered '14:43'	Julia Klopfer (b) (4)	30 Mar 2021 21:32:42

US3432081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User entered '30 Mar 2021 14:43'	System	30 Mar 2021 21:32:42

US3432081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
User entered '97.3' F	Julia Klopfer (b) (4)	30 Mar 2021 21:32:42

US3432081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
User entered 'Oral (Oral)'	Julia Klopfer (b) (4)	30 Mar 2021 21:32:42

US3432081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
User entered empty.	Julia Klopfer (b) (4)	30 Mar 2021 21:32:42

US3432081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
User entered '69'	Julia Klopfer (b) (4)	30 Mar 2021 21:32:42

US3432081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User entered 'bpm'	System	30 Mar 2021 21:32:42

US3432081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
User entered '12'	Julia Klopfer (b) (4)	30 Mar 2021 21:32:42

US3432081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User entered 'breaths/min'	System	30 Mar 2021 21:32:42

US3432081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
User entered '113'	Julia Klopfer (b) (4)	30 Mar 2021 21:32:42

US3432081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User entered 'mmHg'	System	30 Mar 2021 21:32:42

US3432081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
User entered '63'	Julia Klopfer (b) (4)	30 Mar 2021 21:32:42

US3432081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User entered 'mmHg'	System	30 Mar 2021 21:32:42

US3432081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14

US3432081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:31:17

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14

US3432081

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
User entered 'No (N)'	Julia Klopfer (b) (4)	30 Mar 2021 21:32:45

US3432081

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:31:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
User entered empty.	Julia Klopfer (b) (4)	30 Mar 2021 21:32:45

US3432081

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	30 Mar 2021 21:35:46

US3432081

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
User entered '30 Mar 2021'	Julia Klopfer (b) (4)	30 Mar 2021 21:35:46

US3432081

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
User entered '14:58'	Julia Klopfer (b) (4)	30 Mar 2021 21:35:46

US3432081

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User entered '30 Mar 2021 14:58'	System	30 Mar 2021 21:35:46

US3432081

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	30 Mar 2021 21:35:50

US3432081

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 08:30:14
User entered 'I'	System	30 Mar 2021 21:35:50

US3432081

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 10:59:51
User entered 'Yes (Y)'	Tenaizus Woods (b) (4) [REDACTED]	05 Apr 2021 17:26:51

US3432081

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 10:59:51
User entered '5 Apr 2021'	Tenaizus Woods (b) (4) (b) (4)	05 Apr 2021 17:26:51

US3432081

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 10:59:51
User entered 'Contact Made (CONTACT MADE)'	Tenaizus Woods (b) (4) (b) (4)	05 Apr 2021 17:26:51

US3432081

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:31:17

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 10:59:51
User entered empty.	Tenaizus Woods (b) (4) [REDACTED]	05 Apr 2021 17:26:51

US3432081

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	25 Apr 2021 10:59:51
User entered 'Yes (Y)'	Tenaizus Woods (b) (4) (b) (4)	05 Apr 2021 17:26:54

US3432081

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:31:17

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 17:26:54

US3432081

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

Form: Visit Date

Generated On: 09 Jun 2021 17:31:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	12 Feb 2021 21:09:10

US3432081

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

Form: Visit Date

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '12 Feb 2021'	Natalie Izaguirre (b) (4)	12 Feb 2021 21:09:10

US3432081

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

Form: Visit Date

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Clinic (Clinic)'	Natalie Izaguirre (b) (4)	12 Feb 2021 21:09:10

US3432081

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

Form: Visit Date

Generated On: 09 Jun 2021 17:31:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:42:23
User entered 'UNBLND_DECIDE'	System	12 Feb 2021 21:09:10

US3432081

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

Form: Unblinding

Generated On: 09 Jun 2021 17:31:17

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:52
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '12 Feb 2021'	Natalie Izaguirre (b) (4)	12 Feb 2021 21:09:37

US3432081

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

Form: Unblinding

Generated On: 09 Jun 2021 17:31:17

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:52
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:39:28

US3432081

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

Form: Unblinding

Generated On: 09 Jun 2021 17:31:17

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:52
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	12 Feb 2021 21:09:37

US3432081

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

Form: Unblinding

Generated On: 09 Jun 2021 17:31:17

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:52
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
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 03:39:28

US3432081

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

Form: Unblinding

Generated On: 09 Jun 2021 17:31:17

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:52
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '12 Feb 2021'	Natalie Izaguirre (b) (4)	12 Feb 2021 21:09:37

US3432081

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

Form: Unblinding

Generated On: 09 Jun 2021 17:31:17

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:52
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'mRNA-1273 (mRNA-1273)'	Natalie Izaguirre (b) (4)	12 Feb 2021 21:09:37

US3432081

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

Form: Unblinding

Generated On: 09 Jun 2021 17:31:17

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:52
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'mRNA-1273 (mRNA-1273)'	Natalie Izaguirre (b) (4)	12 Feb 2021 21:09:37

US3432081

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

Form: Unblinding

Generated On: 09 Jun 2021 17:31:17

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:52
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'mRNA-1273 (mRNA-1273)'	Natalie Izaguirre (b) (4)	12 Feb 2021 21:09:37

US3432081

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

Form: Unblinding

Generated On: 09 Jun 2021 17:31:17

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:52
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	Natalie Izaguirre (b) (4)	12 Feb 2021 21:09:37

US3432081

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

Form: Unblinding

Generated On: 09 Jun 2021 17:31:17

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:52
User entered empty.	System	12 Feb 2021 21:09:37

US3432081

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

Form: Unblinding

Generated On: 09 Jun 2021 17:31:17

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:52
User entered empty.	System	12 Feb 2021 21:09:37

US3432081

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:52
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	12 Feb 2021 21:09:59

US3432081

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:52
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '12 Feb 2021'	Natalie Izaguirre (b) (4)	12 Feb 2021 21:09:59

US3432081

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:52
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '09:34'	Natalie Izaguirre (b) (4)	12 Feb 2021 21:09:59

US3432081

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:52
User entered '12 Feb 2021 09:34'	System	12 Feb 2021 21:09:59

US3432081

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:31:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:52
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Natalie Izaguirre (b) (4)	12 Feb 2021 21:10:13

US3432081

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:31:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:52
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '12 Feb 2021'	Natalie Izaguirre (b) (4)	12 Feb 2021 21:10:13

US3432081

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:31:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:52
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '09:36'	Natalie Izaguirre (b) (4)	12 Feb 2021 21:10:13

US3432081

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:31:17

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:38:52
User entered '12 Feb 2021 09:36'	System	12 Feb 2021 21:10:13

US3432081

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:31:17

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:52:56
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	23 Jan 2021 15:05:51

US3432081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:17

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:20:25
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:14
User entered	System	25 Jan 2021 15:18:41
'USA-US078-2021-mRNA-1273-P301000009'		
User entered 'New'	(b) (4), (b) (6)	25 Jan 2021 15:18:41

US3432081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:17

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
	(b) (4), (b) (6)	26 Mar 2021 19:53:28
User closed query 'PV Query: It was stated that the surgery was done in another country. Please provide the country in which the event occurred.' (Site from Safety).		
Query 'PV Query: It was stated that the surgery was done in another country. Please provide the country in which the event occurred.' answered with 'country not provided by participant. confirmed' (Site from Safety).	Monica Feeley (b) (4)	25 Mar 2021 21:08:45
User opened query 'PV Query: It was stated that the surgery was done in another country. Please provide the country in which the event occurred.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 13:59:40
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:20:25
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\23.0.	Coder Import (b) (4)	23 Jan 2021 15:09:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	23 Jan 2021 15:09:00
Data point term sent to Coder	System	23 Jan 2021 15:07:40
User entered 'appendicitis'	Julia Klopfer (b) (4)	23 Jan 2021 15:06:58
	(b) (4)	

US3432081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:17

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:20:25
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	23 Jan 2021 15:06:58
	(b) (4)	

US3432081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:17

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:20:25
User entered 'No (N)'	Julia Klopfer (b) (4)	23 Jan 2021 15:06:58
	(b) (4)	

US3432081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:17

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:20:25
User entered 'No (N)'	Julia Klopfer (b) (4)	23 Jan 2021 15:06:58
	(b) (4)	

US3432081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:20:25
User entered '20 Jan 2021'	Julia Klopfer (b) (4)	23 Jan 2021 15:06:58
	(b) (4)	

US3432081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:17

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:20:25
User entered empty.	Julia Klopfer (b) (4)	23 Jan 2021 15:06:58
	(b) (4)	

US3432081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:17

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Jan 2021 15:06:58

US3432081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:20:25
User entered 'No (N)'	Julia Klopfer (b) (4)	23 Jan 2021 15:06:58
	(b) (4)	

US3432081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:17

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:20:25
User entered '21 Jan 2021'	Julia Klopfer (b) (4)	23 Jan 2021 15:06:58
	(b) (4)	

US3432081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:17

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:20:25
User entered empty.	Julia Klopfer (b) (4)	23 Jan 2021 15:06:58
	(b) (4)	

US3432081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:17

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Jan 2021 15:06:58

US3432081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:17

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:20:25
User entered 'Grade 3/Severe (Grade 3/Severe)'	Julia Klopfer (b) (4)	23 Jan 2021 15:06:58
	(b) (4)	

US3432081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:17

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:20:25
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	23 Jan 2021 15:06:58
	(b) (4)	

US3432081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:17

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:20:25
User entered '0'	Julia Klopfer (b) (4)	23 Jan 2021 15:06:58
	(b) (4)	

US3432081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:17

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:20:25
User entered '0'	Julia Klopfer (b) (4)	23 Jan 2021 15:06:58
	(b) (4)	

US3432081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:20:25
User entered 'I'	Julia Klopfer (b) (4)	23 Jan 2021 15:06:58
	(b) (4)	

US3432081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:17

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:20:25
User entered '20 Jan 2021'	Julia Klopfer (b) (4)	23 Jan 2021 15:06:58
	(b) (4)	

US3432081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:17

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:20:25
	(b) (4), (b) (6)	
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).		11 Feb 2021 17:08:52
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'we are unable to obtain this record' (Site from Safety).	Monica Feeley (b) (4)	10 Feb 2021 20:26:55
	(b) (4)	
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 19:59:56
	(b) (4)	
User entered '21 Jan 2021'	Julia Klopfer (b) (4)	23 Jan 2021 15:06:58
	(b) (4)	

US3432081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:17

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:20:25
User entered 'No (N)'	Julia Klopfer (b) (4)	23 Jan 2021 15:06:58
	(b) (4)	

US3432081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:17

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:20:25
User entered empty.	Julia Klopfer (b) (4)	23 Jan 2021 15:06:58
	(b) (4)	

US3432081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:20:25
User entered '0'	Julia Klopfer (b) (4)	23 Jan 2021 15:06:58
	(b) (4)	

US3432081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:20:25
User entered '0'	Julia Klopfer (b) (4)	23 Jan 2021 15:06:58
	(b) (4)	

US3432081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:20:25
User entered '0'	Julia Klopfer (b) (4)	23 Jan 2021 15:06:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:17

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:20:25
User entered 'Not Related (NOT RELATED)'	Julia Klopfer (b) (4)	23 Jan 2021 15:06:58
	(b) (4)	

US3432081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:17

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:20:25
User entered 'Not Related (NOT RELATED)'	Julia Klopfer (b) (4)	23 Jan 2021 15:06:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:17

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:20:25
User entered 'Not Applicable (NOT APPLICABLE)'	Julia Klopfer (b) (4)	23 Jan 2021 15:06:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:17

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:20:25
User entered '0'	Julia Klopfer (b) (4)	23 Jan 2021 15:06:58
	(b) (4)	

US3432081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:17

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR - RQ: Site's response noted. However, CM indication is POST-APPENDECTOMY PAIN MANAGEMENT. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 13:23:55
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
Query 'Per DM CLR - RQ: Site's response noted. However, CM indication is POST-APPENDECTOMY PAIN MANAGEMENT. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify. ' answered with 'it was not taken for appendicitis, it was taken for the surgical procedure appendectomy. By recording "post-appendectomy pain management," we are being the most accurate. We can put appendicitis, but then this is not technically true. ' (Site from DM).	Monica Feeley (b) (4)	02 Apr 2021 20:36:57
User opened query 'Per DM CLR - RQ: Site's response noted. However, CM indication is POST-APPENDECTOMY PAIN MANAGEMENT. Please review if the AE term and CM indication should be reconciled so there will be an appropriate match. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 12:09:42
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 08:56:43

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:17

[Concomitant Medication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'there is very clearly an entry. please see con meds' (Site from DM).	Monica Feeley (b) (4) (b) (4)	25 Mar 2021 21:10:26
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6) (b) (4)	24 Mar 2021 12:09:50
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	16 Mar 2021 17:20:25
User entered 'I'	Julia Klopfer (b) (4) (b) (4)	23 Jan 2021 15:06:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:17

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:20:25
User entered 'I'	Julia Klopfer (b) (4)	23 Jan 2021 15:06:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:17

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:20:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Julia Klopfer (b) (4)	23 Jan 2021 15:06:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:17

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:20:25
User entered empty.	Julia Klopfer (b) (4)	23 Jan 2021 15:06:58
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:17

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	17 Mar 2021 02:14:13
User closed query 'Per source surgery was done in another country, hospital records are in another language and cannot be obtained. please add to narrative' (Site from CRA).	(b) (4), (b) (6)	17 Mar 2021 02:14:11
Query 'Per source surgery was done in another country, hospital records are in another language and cannot be obtained. please add to narrative' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	16 Mar 2021 20:36:32
DataPoint Un-verified.	Monica Feeley (b) (4)	16 Mar 2021 20:36:20
User entered 'PARTICIPANT STARTED EXPERIENCING SYMPTOMS ON 20JAN2021 AND WAS ADMITTED THAT EVENING. PARTICIPANT HAD APPENDIX REMOVED ON 21JAN2021 AND WAS DISCHARGED LATER THAT DAY. COVID TEST 20JAN21 NP, NEGATIVE. Please note, surgery was done in another country and hospital records are unable to be obtained. They are also in another language.' reason for change: Data Entry Error	Monica Feeley (b) (4)	16 Mar 2021 20:36:20
User opened query 'Per source surgery was done in another country, hospital records are in another language and cannot be obtained. please add to narrative' (Site from CRA).	(b) (4), (b) (6)	16 Mar 2021 17:21:26
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:20:25
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Mar 2021 14:58:08
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'COVID test 20JAN21 NP, negative' (Site from Safety).	Monica Feeley (b) (4)	08 Mar 2021 22:07:54

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:17

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PARTICIPANT STARTED EXPERIENCING SYMPTOMS ON 20JAN2021 AND WAS ADMITTED THAT EVENING. PARTICIPANT HAD APPENDIX REMOVED ON 21JAN2021 AND WAS DISCHARGED LATER THAT DAY. COVID test 20JAN21 NP, negative' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	08 Mar 2021 22:07:50
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4)	29 Jan 2021 20:00:08
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	23 Jan 2021 15:09:38
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	23 Jan 2021 15:09:38
User entered 'Participant started experiencing symptoms on 20JAN2021 and was admitted that evening. Participant had appendix removed on 21JAN2021 and was discharged later that day.' reason for change: Data Entry Error	Julia Klopfer (b) (4) (b) (4)	23 Jan 2021 15:09:38
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	23 Jan 2021 15:06:58
User entered empty.	Julia Klopfer (b) (4) (b) (4)	23 Jan 2021 15:06:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:17

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Jan 2021 15:06:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:17

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Jan 2021 15:06:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:31:17

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Jan 2021 15:06:58

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:31:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:52:56
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	10 Aug 2020 21:53:01

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: OTHER GYNECOLOGICALS, ATC: CONTRACEPTIVES FOR TOPICAL USE, ATC: INTRAUTERINE CONTRACEPTIVES, PRODUCT: LEVONORGESTREL, PRODUCTSYNONYM: KYLEENA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 11:56:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 11:56:14
Data point term sent to Coder	System	10 Aug 2020 21:54:25
User entered 'Kyleena IUD'	Julia Klopfer (b) (4)	10 Aug 2020 21:54:11
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User closed query 'Per DM RQ: Thank you for the response. If the medication taken for general health and if the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease, the response for Prophylaxis should be Yes. Please update the response as Yes from No. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 07:42:26
Query 'Per DM RQ: Thank you for the response. If the medication taken for general health and if the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease, the response for Prophylaxis should be Yes. Please update the response as Yes from No. Else, clarify.' answered with 'Updated' (Site from DM).	Alexander Mills (b) (4)	09 Dec 2020 17:10:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Alexander Mills (b) (4)	09 Dec 2020 17:06:51
User opened query 'Per DM RQ: Thank you for the response. If the medication taken for general health and if the recorded medication is either a vaccine, vitamin/supplement, contraceptive or given as prophylaxis/prevention of a disease, the response for Prophylaxis should be Yes. Please update the response as Yes from No. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 04:58:02
User closed query 'Per DM CLR: Indication = CONTRACEPTION. Please review "Prophylaxis = NO" should be marked as "Prophylaxis = YES" instead. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 04:58:02
Query 'Per DM CLR: Indication = CONTRACEPTION. Please review "Prophylaxis = NO" should be marked as "Prophylaxis = YES" instead. Please update accordingly.' answered with 'no' (Site from DM).	Jessica Cauley (b) (4)	13 Nov 2020 15:53:00
User opened query 'Per DM CLR: Indication = CONTRACEPTION. Please review "Prophylaxis = NO" should be marked as "Prophylaxis = YES" instead. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 12:49:07

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	10 Aug 2020 21:54:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Contraception'	Julia Klopfer (b) (4)	10 Aug 2020 21:54:11
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	16 Feb 2021 00:03:29
User entered '1'	Julia Klopfer (b) (4) (b) (4)	10 Aug 2020 21:54:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Other (OTHER)'	Julia Klopfer (b) (4)	10 Aug 2020 21:54:11
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User closed query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 17.5mcg, 7.4mcg etc) instead of IUD count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 05:00:14
Query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 17.5mcg, 7.4mcg etc) instead of IUD count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'unknown, IUD is fine' (Site from DM).	Monica Feeley (b) (4)	25 Nov 2020 21:44:12
User opened query 'Per DM CLR: Please provide the actual dose for this medication (e.g., 17.5mcg, 7.4mcg etc) instead of IUD count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 12:57:15
Query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicate. Please determine if Frequency should be 'continuous', instead. Either update frequency or provide end date. Else, clarify. ' canceled (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 12:56:43
User opened query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicate. Please determine if Frequency should be 'continuous', instead. Either update frequency or provide end date. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 05:47:43
User entered 'IUD'	Julia Klopfer (b) (4)	10 Aug 2020 21:54:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'other (OTHER)'	Julia Klopfer (b) (4)	10 Aug 2020 21:54:11
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User closed query 'Per DM CLR: Please review 'Other Frequency' as IUD term is not a frequency. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 18:42:23
Query 'Per DM CLR: Please review 'Other Frequency' as IUD term is not a frequency. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' answered with 'updated' (Site from DM).	Jessica Cauley (b) (4)	13 Nov 2020 15:53:27
	(b) (4)	
User entered 'continuous' reason for change: Per Query Resolution	Jessica Cauley (b) (4)	13 Nov 2020 15:53:20
	(b) (4)	
User opened query 'Per DM CLR: Please review 'Other Frequency' as IUD term is not a frequency. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 12:57:00
User entered 'IUD'	Julia Klopfer (b) (4)	10 Aug 2020 21:54:11
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Other (OTHER)'	Julia Klopfer (b) (4)	10 Aug 2020 21:54:11
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'TUD'	Julia Klopfer (b) (4)	10 Aug 2020 21:54:11
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 00:30:36
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Julia Klopfer (b) (4)	10 Aug 2020 21:54:29
answered with 'Per protocol, required' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 21:54:11
User entered 'UN UNK 2019'	Julia Klopfer (b) (4)	10 Aug 2020 21:54:11
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	16 Feb 2021 00:03:29
User entered '0'	Julia Klopfer (b) (4) (b) (4)	10 Aug 2020 21:54:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	10 Aug 2020 21:54:11
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:17

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4) [REDACTED]	16 Feb 2021 00:03:29
User entered empty.	Julia Klopfer (b) (4) (b) (4)	10 Aug 2020 21:54:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	Julia Klopfer (b) (4)	10 Aug 2020 21:54:11
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 21:54:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 21:54:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:31:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Aug 2020 21:54:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:13:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Mar 2021 14:18:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Mar 2021 14:18:56
Data point term sent to Coder	System	09 Mar 2021 14:17:50
Coding entries removed.	Phoebe Cunningham	09 Mar 2021 14:17:10
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 18:09:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Sep 2020 18:09:46
Data point term sent to Coder	System	15 Sep 2020 18:09:08
User entered 'Tylenol'	(b) (4), (b) (6)	15 Sep 2020 18:08:53

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:13:00
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 18:08:53

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:13:00
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:59:51
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN AND HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN AND HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 13:24:43
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN AND HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN AND HEADACHE did not meet the AE reporting criteria. ' answered with 'no ae needed. this is from the diary period, which are solicited AEs' (Site from DM).	Monica Feeley (b) (4)	02 Apr 2021 14:49:15

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:17

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN AND HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN AND HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 06:27:26
User closed query 'Per DM CLR: Please update the indication to reflect the location or type of PAIN. Review and update indication and ensure to update Adverse event eCRF as appropriate. Also, review if indication is considered a solicited systemic adverse reaction per protocol 8.3.4. If Yes, consider recording this event in AE. Otherwise, please confirm in query response that the solicited adverse reaction did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 11:35:53
Query 'Per DM CLR: Please update the indication to reflect the location or type of PAIN. Review and update indication and ensure to update Adverse event eCRF as appropriate. Also, review if indication is considered a solicited systemic adverse reaction per protocol 8.3.4. If Yes, consider recording this event in AE. Otherwise, please confirm in query response that the solicited adverse reaction did not meet the AE reporting criteria. ' answered with 'updated to indicate full indication' (Site from DM).	Phoebe Cunningham (b) (4)	09 Mar 2021 14:17:25
Signature has been broken.	Phoebe Cunningham (b) (4)	09 Mar 2021 14:17:10
User entered 'injection site PAIN and headache' reason for change: Data Entry Error	Phoebe Cunningham (b) (4)	09 Mar 2021 14:17:10

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:17

Indication

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the indication to reflect the location or type of PAIN. Review and update indication and ensure to update Adverse event eCRF as appropriate. Also, review if indication is considered a solicited systemic adverse reaction per protocol 8.3.4. If Yes, consider recording this event in AE. Otherwise, please confirm in query response that the solicited adverse reaction did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 09:10:25
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
Query 'Per DM CLR: Please update the condition to include the type and/or location of Pain. Also, note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN did not meet the AE reporting criteria.'	(b) (4), (b) (6)	24 Nov 2020 07:35:48
canceled (Site from DM).		
Query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.	(b) (4), (b) (6)	24 Nov 2020 07:35:46
' canceled (Site from DM).		

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:17

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the condition to include the type and/or location of Pain. Also, note that there is no AE that matches this Con Med indication during this timeframe. If the PAIN is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 13:35:32
User opened query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 11:19:06
Query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' canceled (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 10:55:38
User opened query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update Indication and ensure to reconcile with AE/MH entries so there is an appropriate match.' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 10:54:37
User entered 'pain'	(b) (4), (b) (6)	15 Sep 2020 18:08:53

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:13:00
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '1000'	(b) (4), (b) (6)	15 Sep 2020 18:08:53

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:13:00
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Sep 2020 18:08:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:13:00
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 18:08:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:13:00
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'twice daily (BID)'	(b) (4), (b) (6)	15 Sep 2020 18:08:53

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:13:00
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 18:08:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:13:00
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	15 Sep 2020 18:08:53

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:13:00
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 18:08:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:13:00
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	15 Sep 2020 18:10:55
User entered '9 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 18:10:55
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	15 Sep 2020 18:08:53
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 18:08:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:13:00
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 18:08:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:13:00
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 18:10:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Sep 2020 18:10:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 18:10:55
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 18:08:53
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 18:08:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:13:00
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '9 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 18:10:55
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 18:08:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:13:00
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User closed query 'Per DM CLR: Please review if this Con Med was given to a solicited event as there is a recorded SAR in Diary page that matches this Con Med indication and timeframe. If yes, update the response in this field as appropriate. Else, provide clarification on query response.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 14:19:23
Query 'Per DM CLR: Please review if this Con Med was given to a solicited event as there is a recorded SAR in Diary page that matches this Con Med indication and timeframe. If yes, update the response in this field as appropriate. Else, provide clarification on query response.' answered with 'updated' (Site from DM).	Monica Feeley (b) (4)	02 Feb 2021 15:48:15
User entered 'Yes (Y)' reason for change: Data Entry Error	Monica Feeley (b) (4)	02 Feb 2021 15:48:07
User opened query 'Per DM CLR: Please review if this Con Med was given to a solicited event as there is a recorded SAR in Diary page that matches this Con Med indication and timeframe. If yes, update the response in this field as appropriate. Else, provide clarification on query response.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 13:27:25
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 18:10:55
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Sep 2020 18:10:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Sep 2020 18:10:55
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 18:08:53
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 18:08:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:13:00
User entered '2'	System	15 Sep 2020 18:08:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:13:00
User entered '1'	System	15 Sep 2020 18:08:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:31:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:13:00
User entered '804 (804)'	System	15 Sep 2020 18:08:53

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:17

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:13:04
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 14:38:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 14:38:52
Data point term sent to Coder Coding entries removed.	System Phoebe Cunningham (b) (4)	09 Mar 2021 14:17:50 09 Mar 2021 14:17:45
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 05:47:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 05:47:53
Data point term sent to Coder User entered 'Neproxen'	System (b) (4), (b) (6)	15 Sep 2020 18:18:30 15 Sep 2020 18:17:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:13:04
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 18:17:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:13:04
User signature succeeded.	Lindsey Baden (b) (4)	25 Apr 2021 10:59:51
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN AND HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN AND HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 13:27:01
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN AND HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN AND HEADACHE did not meet the AE reporting criteria. ' answered with 'no ae needed. this is from the diary period, which are solicited AEs' (Site from DM).	Monica Feeley (b) (4)	02 Apr 2021 14:49:23

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:17

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the INJECTION SITE PAIN AND HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of INJECTION SITE PAIN AND HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 06:27:44
User closed query 'Per DM CLR: Please update the indication to reflect the location or type of PAIN. Review and update indication and ensure to update Adverse event eCRF as appropriate. Also, review if indication is considered a solicited systemic adverse reaction per protocol 8.3.4. If Yes, consider recording this event in AE. Otherwise, please confirm in query response that the solicited adverse reaction did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	10 Mar 2021 11:36:15
Query 'Per DM CLR: Please update the indication to reflect the location or type of PAIN. Review and update indication and ensure to update Adverse event eCRF as appropriate. Also, review if indication is considered a solicited systemic adverse reaction per protocol 8.3.4. If Yes, consider recording this event in AE. Otherwise, please confirm in query response that the solicited adverse reaction did not meet the AE reporting criteria. ' answered with 'updated to indicate full indication' (Site from DM).	Phoebe Cunningham (b) (4)	09 Mar 2021 14:17:49
Signature has been broken.	Phoebe Cunningham (b) (4)	09 Mar 2021 14:17:45
User entered 'Injection site PAIN and headache' reason for change: Data Entry Error	Phoebe Cunningham (b) (4)	09 Mar 2021 14:17:45

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:17

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please update the indication to reflect the location or type of PAIN. Review and update indication and ensure to update Adverse event eCRF as appropriate. Also, review if indication is considered a solicited systemic adverse reaction per protocol 8.3.4. If Yes, consider recording this event in AE. Otherwise, please confirm in query response that the solicited adverse reaction did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 09:10:49
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
Query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.	(b) (4), (b) (6)	24 Nov 2020 07:36:00
' canceled (Site from DM).		
User opened query 'Per DM CLR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.	(b) (4), (b) (6)	26 Oct 2020 11:18:33
' (Site from DM).		
User entered 'PAIN'	(b) (4), (b) (6)	15 Sep 2020 18:17:52

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:13:04
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '250'	(b) (4), (b) (6)	15 Sep 2020 18:17:52

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:13:04
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'mg (mg)'	(b) (4), (b) (6)	15 Sep 2020 18:17:52

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:13:04
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 18:17:52

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:13:04
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'once daily (QD)'	(b) (4), (b) (6)	15 Sep 2020 18:17:52

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:13:04
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 18:17:52

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:13:04
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	15 Sep 2020 18:17:52

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:13:04
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	(b) (4), (b) (6)	15 Sep 2020 18:17:52

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:13:04
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '9 Sep 2020'	(b) (4), (b) (6)	15 Sep 2020 18:17:52

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:13:04
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '0'	(b) (4), (b) (6)	15 Sep 2020 18:17:52

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:13:04
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 18:17:52

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:13:04
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '9 Sep 2020'	(b) (4), (b) (6)	15 Sep 2020 18:17:52

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:13:04
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User closed query 'Per DM CLR: Please review if this Con Med was given to a solicited event as there is a recorded SAR in Diary page that matches this Con Med indication and timeframe. If yes, update the response in this field as appropriate. Else, provide clarification on query response.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 14:18:58
Query 'Per DM CLR: Please review if this Con Med was given to a solicited event as there is a recorded SAR in Diary page that matches this Con Med indication and timeframe. If yes, update the response in this field as appropriate. Else, provide clarification on query response.' answered with 'updated' (Site from DM).	Monica Feeley (b) (4)	02 Feb 2021 15:48:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Monica Feeley (b) (4)	02 Feb 2021 15:48:33
User opened query 'Per DM CLR: Please review if this Con Med was given to a solicited event as there is a recorded SAR in Diary page that matches this Con Med indication and timeframe. If yes, update the response in this field as appropriate. Else, provide clarification on query response.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 13:23:50
User entered 'No (N)'	(b) (4), (b) (6)	15 Sep 2020 18:17:52

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:13:04
User entered '1'	System	15 Sep 2020 18:17:52

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:13:04
User entered '1'	System	15 Sep 2020 18:17:52

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:31:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 02:13:04
User entered '804 (804)'	System	15 Sep 2020 18:17:52

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:17

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:06:42
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 16:07:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 16:07:42
Data point term sent to Coder	System	29 Sep 2020 16:07:01
User entered 'Influenza Vaccine'	(b) (4), (b) (6)	29 Sep 2020 16:06:25

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:17

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:06:42
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Sep 2020 16:06:25

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:17

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:06:42
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Influenza prophylaxis'	(b) (4), (b) (6)	29 Sep 2020 16:06:25

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:17

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:06:42
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'I'	(b) (4), (b) (6)	29 Sep 2020 16:06:25

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:17

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:06:42
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Other (OTHER)'	(b) (4), (b) (6)	29 Sep 2020 16:06:25

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:17

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:06:42
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'vaccination'	(b) (4), (b) (6)	29 Sep 2020 16:06:25

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:17

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:06:42
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'once (ONCE)'	(b) (4), (b) (6)	29 Sep 2020 16:06:25

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:17

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:06:42
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 16:06:25

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:17

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:06:42
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	29 Sep 2020 16:06:25

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:17

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:06:42
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	(b) (4), (b) (6)	29 Sep 2020 16:06:25

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:06:42
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '29 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 16:06:25

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:06:42
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '0'	(b) (4), (b) (6)	29 Sep 2020 16:06:25

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:17

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:06:42
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 16:06:25

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:06:42
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '29 Sep 2020'	(b) (4), (b) (6)	29 Sep 2020 16:06:25

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:06:42
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	(b) (4), (b) (6)	29 Sep 2020 16:06:25

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:06:42
User entered empty.	System	29 Sep 2020 16:06:25

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:06:42
User entered empty.	System	29 Sep 2020 16:06:25

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:31:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 05:06:42
User entered empty.	System	29 Sep 2020 16:06:25

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:17

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:14:51
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Jan 2021 19:30:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Jan 2021 19:30:05
Data point term sent to Coder	System	23 Jan 2021 19:28:39
User entered 'tylenol'	Julia Klopfer (b) (4)	23 Jan 2021 19:27:49

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:17

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:14:51
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	Julia Klopfer (b) (4)	23 Jan 2021 19:27:49

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:17

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:14:51
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'post-appendectomy pain management'	Julia Klopfer (b) (4)	23 Jan 2021 19:27:49

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:17

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:14:51
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'I'	Julia Klopfer (b) (4)	23 Jan 2021 19:27:49

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:17

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:14:51
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'tablet (TABLET)'	Julia Klopfer (b) (4)	23 Jan 2021 19:27:49

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:17

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:14:51
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	Julia Klopfer (b) (4)	23 Jan 2021 19:27:49

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:17

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:14:51
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'as needed (PRN)'	Julia Klopfer (b) (4)	23 Jan 2021 19:27:49

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:17

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:14:51
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	Julia Klopfer (b) (4)	23 Jan 2021 19:27:49

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:17

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:14:51
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Oral (ORAL)'	Julia Klopfer (b) (4)	23 Jan 2021 19:27:49

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:17

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:14:51
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	Julia Klopfer (b) (4)	23 Jan 2021 19:27:49

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:14:51
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '21 Jan 2021'	Julia Klopfer (b) (4)	23 Jan 2021 19:27:49

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:14:51
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '0'	Julia Klopfer (b) (4)	23 Jan 2021 19:27:49

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:17

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:14:51
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	Julia Klopfer (b) (4)	23 Jan 2021 19:27:49

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:14:51
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	Julia Klopfer (b) (4)	23 Jan 2021 19:27:49

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:14:51
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	Julia Klopfer (b) (4)	23 Jan 2021 19:27:49

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:17

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Jan 2021 19:27:49

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:17

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Jan 2021 19:27:49

US3432081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:31:17

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Jan 2021 19:27:49

US3432081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:31:17

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:52:56
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User closed query 'Per CDM: 'Were any concomitant procedures performed?' is NO, however a procedure is recorded. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 14:19:42
Query 'Per CDM: 'Were any concomitant procedures performed?' is NO, however a procedure is recorded. Please review and update as appropriate.' answered with 'updated' (Site from DM).	Monica Feeley (b) (4)	02 Feb 2021 14:32:34
User entered 'Yes (Y)' reason for change: Data Entry Error	Monica Feeley (b) (4)	02 Feb 2021 14:32:17
User opened query 'Per CDM: 'Were any concomitant procedures performed?' is NO, however a procedure is recorded. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 14:04:02
User entered 'No (N)' reason for change: Data Entry Error	Alexander Mills (b) (4)	09 Dec 2020 17:13:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 20:18:13

US3432081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:31:17

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:28:16
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '21 Jan 2021'	Julia Klopfer (b) (4)	23 Jan 2021 19:26:46

US3432081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:31:17

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:28:18
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Appendectomy'	Julia Klopfer (b) (4)	23 Jan 2021 19:26:46

US3432081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:31:17

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:28:19
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Adverse Event (AE)'	Julia Klopfer (b) (4)	23 Jan 2021 19:26:46

US3432081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:31:17

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:28:21
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered empty.	Julia Klopfer (b) (4)	23 Jan 2021 19:26:46

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'USA-US078-2021-MRNA-1273-P301000009'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Lindsey'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Baden'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'MA'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'US'	System	25 Jan 2021 15:18:55

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	17 Mar 2021 19:21:16
User entered '2'	System	09 Mar 2021 14:58:53
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '1'	System	25 Jan 2021 15:18:55

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'USA-US078-2021-MRNA-1273-P301000009'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Lindsey'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Baden'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'MA'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'US'	System	25 Jan 2021 15:18:55

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	17 Mar 2021 19:21:16
User entered '2'	System	09 Mar 2021 14:58:53
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '1'	System	25 Jan 2021 15:18:55

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:31:17

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '25/Jan/2021 10:18'	System	25 Jan 2021 15:18:55

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:31:17

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 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'I'	(b) (4), (b) (6)	25 Jan 2021 15:18:55

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'USA-US078-2021-MRNA-1273-P301000009'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Lindsey'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Baden'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'MA'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'US'	System	25 Jan 2021 15:18:55

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	17 Mar 2021 19:21:16
User entered '2'	System	09 Mar 2021 14:58:53
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '1'	System	25 Jan 2021 15:18:55

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:31:17

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
User entered '09/Mar/2021 09:58'	System	09 Mar 2021 14:58:53

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:31:17

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 20:32:45
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
User entered 'I'	(b) (4), (b) (6)	09 Mar 2021 14:58:53

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'USA-US078-2021-MRNA-1273-P301000009'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Yes (Y)'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'No (N)'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Lindsey'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'Baden'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'MA'	System	25 Jan 2021 15:18:41

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 17:27:07
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 14:58:40
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered 'US'	System	25 Jan 2021 15:18:55

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 17:31:17

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	17 Mar 2021 19:21:16
User entered '2'	System	09 Mar 2021 14:58:53
User signature succeeded.	Lindsey Baden (b) (4)	16 Feb 2021 00:03:29
User entered '1'	System	25 Jan 2021 15:18:55

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:31:17

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 14:51:32
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
User entered '17/Mar/2021 15:21'	System	17 Mar 2021 19:21:16

US3432081

Folder: SAE USA-US078-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:31:17

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)	14 Apr 2021 14:51:32
User signature succeeded.	Lindsey Baden (b) (4)	04 Apr 2021 20:32:45
User entered 'I'	(b) (4), (b) (6)	17 Mar 2021 19:21:16