

US3812293 (Prod: Sundance Clinical Research - Platinum - PPDS)

Generated By: (b) (6)

Generated On: 26 Nov 2020 11:20:44

All time stamps listed in this document are displayed in GMT

US3812293

Form: Participant Creation

Generated On: 26 Nov 2020 11:20:44

Participant ID

US3812293

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

US3812293

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	28 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

Date of Birth (MMM yyyy)	(b) (6) 1969
Age	51
Age Units	YEARS
Age (Derived)	51
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☐ Not Hispanic or Latino ☒ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:20:44

Date of Informed Consent (<i>dd MMM yyyy</i>)	28 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐
	Amendment 2 ☒
	Amendment 3 ☐
	Amendment 4 ☐
	Amendment 5 ☐
Was participant enrolled in the study?	Yes ☒
	No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐
	Inclusion/Exclusion ☐
	Cohort Full ☐
	Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐
	No ☒
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:20:44

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:20:44

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:20:44

Condition	MENOPAUSE
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:20:44

Condition	BILATERAL TUBAL LIGATION
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2000
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	JAN 2000
Stop Year (derived)	2000

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:20:44

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:20:44

Condition	ACID REFLUX
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:20:44

Condition	BILATERAL VISION IMPAIRMENT
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:20:44

Condition	VICODIN ALLERGY
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:20:44

Condition	ENVIRONMENTAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1980
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:20:44

Condition	DEPRESSIOIN
Start date (dd MMM yyyy)	UN UNK 1990
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	28 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	13:16 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 13:16
Height (<i>xxx.x</i>)	64.5 in
Weight (<i>xxx.x</i>)	214.6 lb
BMI (<i>xxx.x</i>)	36.34295 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	98.2 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	62 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	72 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:20:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 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

Generated On: 26 Nov 2020 11:20:44

Date of assessment (<i>dd MMM yyyy</i>)	28 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 (<i>dd MMM yyyy</i>)	UN UNK 2000
Date of surgery unknown	False
If Post-menopausal, date of last menstruation (<i>dd MMM yyyy</i>)	
Date of last menstruation unknown	False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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	True
Resides in Nursing Home or Assisted Living Facility	False
Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False

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Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	28 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:20:44

What was the date of randomization? (dd MMM yyyy) 28 AUG 2020

What was the participant's randomization number? 109586

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:20:44

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☒ Post-Dose ☐
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	28 AUG 2020
Time of assessment (00:00-23:59)	13:16 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 13:16
Temperature (xxx.x)	98.2 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ☒
Were vital signs assessed?	Yes ☒ No ☐
Date of assessment (dd MMM yyyy)	28 AUG 2020
Time of assessment (00:00-23:59)	14:30 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 14:30
Temperature (xxx.x)	98.3 F
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:20:44

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: Exposure

Generated On: 26 Nov 2020 11:20:44

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) 28 AUG 2020

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

Treatment Date and Time (derived) 28 AUG 2020 13:59

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

28 AUG 2020

Collection time (*00:00-23:59*)

13:46 (24 HR)

Collection date and time (derived)

28 AUG 2020 13:46

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:20:44

Collection date (<i>dd MMM yyyy</i>)			28 AUG 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:51	28 AUG 2020 13:51
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

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: 26 Nov 2020 11:20:44

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

98.7 °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 28 AUG 2020 14:21

PC Open Date & Time 28 AUG 2020 14:19

PC Close Date & Time 28 AUG 2020 16:49

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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 98.5 °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	28 AUG 2020 18:23
PC Open Date & Time	28 AUG 2020 17:44
PC Close Date & Time	29 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 12:00

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

30 AUG 2020 13:09

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

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

96.7 °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

31 AUG 2020 13:30

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

01 SEP 2020 12:02

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 13:11

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

03 SEP 2020 12:11

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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

28 AUG 2020 14:22

PC Open Date & Time

28 AUG 2020 14:19

PC Close Date & Time

28 AUG 2020 16:49

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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

28 AUG 2020 18:24

PC Open Date & Time

28 AUG 2020 17:44

PC Close Date & Time

29 AUG 2020 11:59

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

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

29 AUG 2020 12:01

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

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

30 AUG 2020 13:09

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

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

31 AUG 2020 13:30

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

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

01 SEP 2020 12:03

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

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

02 SEP 2020 13:11

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

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

03 SEP 2020 12:12

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 14:23
PC Open Date & Time	28 AUG 2020 14:19
PC Close Date & Time	28 AUG 2020 16:49

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 18:24
PC Open Date & Time	28 AUG 2020 17:44
PC Close Date & Time	29 AUG 2020 11:59

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

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 ☒

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

Yes ☐	
PC Time stamp	29 AUG 2020 12:02
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

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 ☒

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

Yes ☐	
PC Time stamp	30 AUG 2020 13:11
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

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 ☒

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

Yes ☐	
PC Time stamp	31 AUG 2020 13:31
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

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 ☒

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

Yes ☐	
PC Time stamp	01 SEP 2020 12:04
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

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 ☒

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

Yes ☐	
PC Time stamp	02 SEP 2020 13:12
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

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 ☒

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

Yes ☐	
PC Time stamp	03 SEP 2020 12:12
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 04 SEP 2020 17:55

PC Open Date & Time 04 SEP 2020 12:00

PC Close Date & Time 05 SEP 2020 11:59

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 05 SEP 2020 12:11

PC Open Date & Time 05 SEP 2020 12:00

PC Close Date & Time 06 SEP 2020 11:59

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

06 SEP 2020 13:07

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

07 SEP 2020 12:03

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

08 SEP 2020 16:29

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

09 SEP 2020 12:00

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

10 SEP 2020 14:55

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

11 SEP 2020 12:11

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 16

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

12 SEP 2020 12:12

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	04 SEP 2020 17:55
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	05 SEP 2020 12:12
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	06 SEP 2020 13:07
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	07 SEP 2020 12:03
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 12

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

No ☐

Yes ☒

PC Time stamp

08 SEP 2020 16:29

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 13

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

No ☐

Yes ☒

PC Time stamp

09 SEP 2020 12:01

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	10 SEP 2020 14:55
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 15

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

No ☒

Yes ☐

PC Time stamp

11 SEP 2020 12:11

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT	DAY 16
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	12 SEP 2020 12:12
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3812293

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

Was Contact Attempted?

Yes ☒

No ☐

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

04 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812293

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812293

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812293

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812293

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812293

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812293

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	28 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3812293

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	28 SEP 2020
Time of assessment (00:00-23:59)	13:56 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 13:56
Temperature (xxx.x)	96.8 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3812293

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☐
	No ☒
Date of assessment (dd MMM yyyy)	
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	
Pulse units	
Respiratory Rate (xxx)	
Respiratory Rate units	
Systolic Blood Pressure (xxx)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (xxx)	
Diastolic Blood Pressure units	

US3812293

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:20:44

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.

US3812293

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

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? _____

What was the treatment date? (dd MMM yyyy) _____

What was the treatment time? (00:00-23:59) _____

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3812293

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	28 SEP 2020
Collection time (<i>00:00-23:59</i>)	14:25 (24 HR)
Collection date and time (derived)	28 SEP 2020 14:25

US3812293

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:20:44

Collection date (<i>dd MMM yyyy</i>)			28 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:30	28 SEP 2020 14:30
Nasopharyngeal Swab 2	No		

US3812293

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812293

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812293

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812293

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812293

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812293

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812293

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812293

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	23 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3812293

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	23 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	14:25 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 14:25
Temperature (<i>xxx.x</i>)	97.1 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	66 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812293

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:20:44

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.

US3812293

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	23 OCT 2020
Collection time (<i>00:00-23:59</i>)	14:35 (24 HR)
Collection date and time (derived)	23 OCT 2020 14:35

US3812293

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812293

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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	01 NOV 2020 09:44:36
Patient Cloud Open Date & Time	28 OCT 2020 00:01
Patient Cloud Close Date & Time	01 NOV 2020 23:59

US3812293

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

04 NOV 2020 02:38:59

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3812293

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 NOV 2020 09:09:10

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

29 OCT 2020 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

05 NOV 2020 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

12 NOV 2020 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

19 NOV 2020 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 08:03:31
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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03 DEC 2020 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

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06 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

10 DEC 2020 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

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13 DEC 2020 00:01

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US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

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20 DEC 2020 00:01

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US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

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US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

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US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JAN 2021 00:01

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US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JAN 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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04 FEB 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 166

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

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

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

11 FEB 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

14 FEB 2021 00:01

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18 FEB 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

25 FEB 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

04 MAR 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAR 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

14 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAR 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT	DAY 208
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

25 MAR 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

01 APR 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

08 APR 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 229

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

11 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 APR 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

22 APR 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

29 APR 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT	DAY 257
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 306

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

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

No ☐

Yes ☐

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

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

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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUL 2021 00:01

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22 JUL 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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19 AUG 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 362

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

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

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

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

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

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

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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

10 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

14 OCT 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

14 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2021 00:01

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23 DEC 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐ Yes ☐

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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30 DEC 2021 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 495

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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06 JAN 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

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13 JAN 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

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20 JAN 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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 JAN 2022 00:01

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27 JAN 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

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03 FEB 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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10 FEB 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

13 FEB 2022 00:01

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17 FEB 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

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24 FEB 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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03 MAR 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

13 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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31 MAR 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

10 APR 2022 00:01

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14 APR 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2022 00:01

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21 APR 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2022 00:01

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28 APR 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

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05 MAY 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

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05 JUN 2022 00:01

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09 JUN 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐ Yes ☐

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

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19 JUN 2022 00:01

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23 JUN 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

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26 JUN 2022 00:01

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30 JUN 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

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03 JUL 2022 00:01

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07 JUL 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

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10 JUL 2022 00:01

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14 JUL 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

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17 JUL 2022 00:01

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21 JUL 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

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28 JUL 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

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31 JUL 2022 00:01

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04 AUG 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

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07 AUG 2022 00:01

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11 AUG 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

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14 AUG 2022 00:01

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18 AUG 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

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28 AUG 2022 00:01

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01 SEP 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

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04 SEP 2022 00:01

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08 SEP 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2022 23:59

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 ☐ Yes ☐

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

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2022 23:59

US3812293

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3812293

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812293

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

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

US3812293

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3812293

Folder: Covid-19 Assessment 28 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:20:44

Date of Contact	28 AUG 2020
Time of Contact	12:57
Date and Time of Contact (derived)	28 AUG 2020 12:57
Type of Contact	Clinic Visit - Scheduled ☒
	Clinical Visit - Unscheduled ☐
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☐
	No ☒

US3812293

Folder: Covid-19 Assessment 28 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:20:44

[Generate Next COVID-19 Assessment](#)

Yes ☐
No ☒

US3812293

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:20:44

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3812293

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

AEID	
Adverse event	LEFT AXILLARY ABSCESS
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	06 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	17 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☒ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False

v6.020 DTW (1102)

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US3812293

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

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

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:20:44

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

Yes ☒

No ☐

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

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

Name of Medication	LISINOPRIL
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
Dose per administration	5
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

Name of Medication	MULTI VITAMIN
Prophylaxis	Yes ☒ No ☐
Indication	GENERAL HEALTH
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☒ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2000
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

Name of Medication	TRAMADOL
Prophylaxis	Yes ☐ No ☒
Indication	PAIN AT I&D SITE
Dose per administration	50
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		07 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		07 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☐

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

Name of Medication	CEPHALEXIN
Prophylaxis	Yes ☐ No ☒
Indication	ABSCESS
Dose per administration	500
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		07 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		17 SEP 2020
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3812293

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:20:44

[Were any concomitant procedures performed?](#)

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3812293

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 11:20:44

Procedure/Surgery date (<i>dd MMM yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
7 SEP 2020	INCISION AND DRAINAGE	Adverse Event	

US3812293

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:20:44

Date of dosing discontinuation (dd MMM yyyy)

28 AUG 2020

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 _____

US3812293

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 11:20:44

Date of study discontinuation/completion (dd MMM yyyy)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

Audit

US3812293 (Prod: Sundance Clinical Research - Platinum - PPDS)

US3812293

Form: Participant Creation

Generated On: 26 Nov 2020 11:20:44

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3812293'	RWS_ENDPOINT ENDPOINT (b) (4) 	28 Aug 2020 18:04:28

US3812293

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	28 Aug 2020 19:07:02

US3812293

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '28 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	28 Aug 2020 18:04:29

US3812293

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Heather Cherniawski (b) (4)	28 Aug 2020 19:07:02

US3812293

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	28 Aug 2020 19:07:02

US3812293

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:42:41
User entered (b) (6) 1969'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 18:04:30

US3812293

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[Age](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:42:41
User entered '51'	Heather Cherniawski (b) (4)	28 Aug 2020 19:10:09

US3812293

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	28 Aug 2020 19:10:09

US3812293

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '51'	System	28 Aug 2020 19:07:16

US3812293

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[Sex](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:42:41
User entered 'Female (F)'	Heather Cherniawski (b) (4)	28 Aug 2020 19:10:09

US3812293

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[Ethnicity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:42:41
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Heather Cherniawski (b) (4)	28 Aug 2020 19:10:09

US3812293

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[White](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:42:41
User entered '1'	Heather Cherniawski (b) (4)	28 Aug 2020 19:10:09

US3812293

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[Black](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:42:41
User entered '0'	Heather Cherniawski (b) (4)	28 Aug 2020 19:10:09

US3812293

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[Asian](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:42:41
User entered '0'	Heather Cherniawski (b) (4)	28 Aug 2020 19:10:09

US3812293

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:42:41
User entered '0'	Heather Cherniawski (b) (4)	28 Aug 2020 19:10:09

US3812293

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:42:41
User entered '0'	Heather Cherniawski (b) (4)	28 Aug 2020 19:10:09

US3812293

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:42:41
User entered '0'	Heather Cherniawski (b) (4)	28 Aug 2020 19:10:09

US3812293

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[If race is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:42:41
User entered empty.	Heather Cherniawski (b) (4)	28 Aug 2020 19:10:09

US3812293

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[Unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:42:41
User entered '0'	Heather Cherniawski (b) (4)	28 Aug 2020 19:10:09

US3812293

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 11:20:44

[Not reported](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:42:41
User entered '0'	Heather Cherniawski (b) (4)	28 Aug 2020 19:10:09

US3812293

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:20:44

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:43:04
User entered '28 Aug 2020'	Heather Cherniawski (b) (4)	28 Aug 2020 19:07:16

US3812293

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	28 Aug 2020 19:07:16

US3812293

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '2020'	System	28 Aug 2020 19:07:16

US3812293

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:20:44

[Protocol Version](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:43:04
User entered 'Amendment 2 (2)'	Heather Cherniawski (b) (4)	28 Aug 2020 19:07:16

US3812293

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:43:04
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	28 Aug 2020 19:07:16

US3812293

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:43:04
User entered empty.	Heather Cherniawski (b) (4)	28 Aug 2020 19:07:16

US3812293

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:20:44

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:43:04
User entered empty.	Heather Cherniawski (b) (4)	28 Aug 2020 19:07:16

US3812293

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:20:44

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:43:04
User entered 'No (N)'	Heather Cherniawski (b) (4)	28 Aug 2020 19:07:16

US3812293

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:20:44

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:43:04
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 18:04:29

US3812293

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 11:20:44

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Aug 2020 19:07:21

US3812293

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:43:17
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	28 Aug 2020 19:07:21

US3812293

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 11:20:44

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:43:55
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:25:27

US3812293

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:20:44

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Menopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 23:26:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 23:26:41
Data point term sent to Coder	System	05 Sep 2020 23:25:50
User entered 'MENOPAUSE'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:25:42

US3812293

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered 'UN UNK 2018'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:25:42

US3812293

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered '0'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:25:42

US3812293

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:20:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:25:42

US3812293

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered empty.	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:25:42

US3812293

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:20:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered '0'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:25:42

US3812293

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	05 Sep 2020 23:25:42

US3812293

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '2018'	System	05 Sep 2020 23:25:42

US3812293

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	05 Sep 2020 23:25:42

US3812293

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	05 Sep 2020 23:25:42

US3812293

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:20:44

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 23:27:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	05 Sep 2020 23:27:42
Data point term sent to Coder	System	05 Sep 2020 23:26:50
User entered 'BILATERAL TUBAL LIGATION'	Angie Kean (b) (4)	05 Sep 2020 23:25:59
	(b) (4)	

US3812293

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered 'UN UNK 2000'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:25:59

US3812293

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered '0'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:25:59

US3812293

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:20:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:25:59

US3812293

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered 'UN UNK 2000'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:25:59

US3812293

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:20:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered '0'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:25:59

US3812293

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	05 Sep 2020 23:25:59

US3812293

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '2000'	System	05 Sep 2020 23:25:59

US3812293

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	05 Sep 2020 23:25:59

US3812293

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '2000'	System	05 Sep 2020 23:25:59

US3812293

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:20:44

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Please confirm if subject is taking medication for condition. Thank you.' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 16:02:56
Query 'Please confirm if subject is taking medication for condition. Thank you.' answered with 'The subject is taking lisinopril' (Site from CRA).	Lyly Dang (b) (4)	26 Oct 2020 18:29:36
User opened query 'Please confirm if subject is taking medication for condition. Thank you.' (Site from CRA).	(b) (4), (b) (6)	05 Oct 2020 20:38:53
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 23:27:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 23:27:42
Data point term sent to Coder	System	05 Sep 2020 23:26:52
User entered 'HYPERTENSION'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:26:14

US3812293

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered 'UN UNK 2018'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:26:14

US3812293

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered '0'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:26:14

US3812293

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:20:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:26:14

US3812293

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered empty.	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:26:14

US3812293

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:20:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered '0'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:26:14

US3812293

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	05 Sep 2020 23:26:14

US3812293

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '2018'	System	05 Sep 2020 23:26:14

US3812293

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	05 Sep 2020 23:26:14

US3812293

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	05 Sep 2020 23:26:14

US3812293

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:20:44

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 23:27:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 23:27:42
Data point term sent to Coder	System	05 Sep 2020 23:26:50
User entered 'ACID REFLUX'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:26:24

US3812293

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered 'UN UNK 2015'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:26:24

US3812293

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered '0'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:26:24

US3812293

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:20:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:26:24

US3812293

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered empty.	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:26:24

US3812293

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:20:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered '0'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:26:24

US3812293

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	05 Sep 2020 23:26:24

US3812293

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '2015'	System	05 Sep 2020 23:26:24

US3812293

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	05 Sep 2020 23:26:24

US3812293

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	05 Sep 2020 23:26:24

US3812293

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:20:44

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Visual impairment and blindness (excl colour blindness), PT: Visual impairment, LLT: Visual impairment - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 23:27:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 23:27:42
Data point term sent to Coder	System	05 Sep 2020 23:26:52
User entered 'BILATERAL VISION IMPAIRMENT'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:26:40

US3812293

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered 'UN UNK 1980'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:26:40

US3812293

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered '0'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:26:40

US3812293

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:20:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:26:40

US3812293

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered empty.	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:26:40

US3812293

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:20:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered '0'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:26:40

US3812293

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Jan 1980'	System	05 Sep 2020 23:26:40

US3812293

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '1980'	System	05 Sep 2020 23:26:40

US3812293

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	05 Sep 2020 23:26:40

US3812293

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	05 Sep 2020 23:26:40

US3812293

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:20:44

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 23:28:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	05 Sep 2020 23:28:42
Data point term sent to Coder	System	05 Sep 2020 23:27:55
User entered 'VICODIN ALLERGY'	Angie Kean (b) (4)	05 Sep 2020 23:26:55
	(b) (4)	

US3812293

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered 'UN UNK 1990'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:26:55

US3812293

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered '0'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:26:55

US3812293

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:20:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:26:55

US3812293

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered empty.	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:26:55

US3812293

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:20:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered '0'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:26:55

US3812293

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	05 Sep 2020 23:26:55

US3812293

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '1990'	System	05 Sep 2020 23:26:55

US3812293

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	05 Sep 2020 23:26:55

US3812293

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	05 Sep 2020 23:26:55

US3812293

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:20:44

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Environmental allergy - version MedDRA\23.0.	Coder Import (b) (4)	05 Sep 2020 23:28:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	05 Sep 2020 23:28:43
Data point term sent to Coder	System	05 Sep 2020 23:27:55
User entered 'ENVIRONMENTAL ALLERGIES'	Angie Kean (b) (4)	05 Sep 2020 23:27:08
	(b) (4)	

US3812293

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered 'UN UNK 1980'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:27:08

US3812293

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered '0'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:27:08

US3812293

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:20:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:27:08

US3812293

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered empty.	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:27:08

US3812293

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:20:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered '0'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:27:08

US3812293

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Jan 1980'	System	05 Sep 2020 23:27:08

US3812293

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '1980'	System	05 Sep 2020 23:27:08

US3812293

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	05 Sep 2020 23:27:08

US3812293

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	05 Sep 2020 23:27:08

US3812293

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:20:44

[Condition](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 23:28:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	05 Sep 2020 23:28:42
Data point term sent to Coder	System	05 Sep 2020 23:27:53
User entered 'DEPRESSIOIN'	Angie Kean (b) (4)	05 Sep 2020 23:27:17
	(b) (4)	

US3812293

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered 'UN UNK 1990'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:27:17

US3812293

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered '0'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:27:17

US3812293

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:20:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:27:17

US3812293

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered empty.	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:27:17

US3812293

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:20:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:44:35
User entered '0'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:27:17

US3812293

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	05 Sep 2020 23:27:17

US3812293

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '1990'	System	05 Sep 2020 23:27:17

US3812293

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	05 Sep 2020 23:27:17

US3812293

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	05 Sep 2020 23:27:17

US3812293

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:45:42
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:29:39

US3812293

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:45:42
User entered '28 Aug 2020'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:29:39

US3812293

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:45:42
User entered '13:16'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:29:39

US3812293

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '28 Aug 2020 13:16'	System	05 Sep 2020 23:29:39

US3812293

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:45:42
User entered '64.5' in	Angie Kean (b) (4)	05 Sep 2020 23:29:39
DataPoint set to visible.	(b) (4) System	28 Aug 2020 19:07:21

US3812293

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:45:42
User entered '214.6' lb	Angie Kean (b) (4)	05 Sep 2020 23:29:39
DataPoint set to visible.	(b) (4) System	28 Aug 2020 19:07:21

US3812293

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

BMI (xxx.x)

Audit	User	Time (GMT)
User entered '36.34295'	System	05 Sep 2020 23:29:39
DataPoint set to visible.	System	28 Aug 2020 19:07:21

US3812293

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	05 Sep 2020 23:29:39
DataPoint set to visible.	System	28 Aug 2020 19:07:21

US3812293

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:45:42
User entered '98.2' F	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:29:39

US3812293

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:45:42
User entered 'Oral (Oral)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:29:39

US3812293

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:45:42
User entered empty.	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:29:39

US3812293

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:45:42
User entered '62'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:29:39

US3812293

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Sep 2020 23:29:39

US3812293

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:45:42
User entered '14'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:29:39

US3812293

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Sep 2020 23:29:39

US3812293

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:45:42
User entered '124'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:29:39

US3812293

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Sep 2020 23:29:39

US3812293

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:45:42
User entered '72'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:29:39

US3812293

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Sep 2020 23:29:39

US3812293

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:20:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:46:13
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:29:01

US3812293

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 11:20:44

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:46:13
User entered '28 Aug 2020'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:29:01

US3812293

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:20:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:46:26
User entered '28 Aug 2020'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:27:48

US3812293

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:46:26
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:27:48

US3812293

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:46:26
User entered 'Surgically sterile (SURGICALLY STERILE)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:27:48

US3812293

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:20:44

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:46:26
User entered empty.	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:27:48

US3812293

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:46:26
User closed query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	System	02 Oct 2020 21:51:57
User entered 'un UNK 2000' reason for change: Data Entry Error	Anya Penly (b) (4) (b) (4)	02 Oct 2020 21:51:57
User opened query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	System	05 Sep 2020 23:27:48
User entered empty.	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:27:48

US3812293

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:20:44

Date of surgery unknown

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:46:26
User entered '0'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:27:48

US3812293

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:46:26
User entered empty.	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:27:48

US3812293

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 11:20:44

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:46:26
User entered '0'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:27:48

US3812293

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:48:12
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:28:29

US3812293

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:48:12
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:28:29

US3812293

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:48:12
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:28:29

US3812293

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:48:12
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:28:29

US3812293

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:48:12
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:28:29

US3812293

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:48:12
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:28:29

US3812293

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:48:12
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:28:29

US3812293

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:48:12
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:28:29

US3812293

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:48:12
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:28:29

US3812293

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:48:12
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:28:29

US3812293

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:48:12
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:28:29

US3812293

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

[Other](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:48:12
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:28:29

US3812293

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:48:12
User entered empty.	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:28:29

US3812293

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

No Risk Identified

Audit	User	Time (GMT)
User entered '1'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:28:29

US3812293

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:48:12
User entered '0'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:28:29

US3812293

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:48:12
User entered '0'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:28:29

US3812293

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:48:12
User entered '0'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:28:29

US3812293

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:48:12
User entered '0'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:28:29

US3812293

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:48:12
User entered '0'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:28:29

US3812293

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:28:29

US3812293

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 11:20:44

[Specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:48:12
User entered empty.	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:28:29

US3812293

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:53:22
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	28 Aug 2020 19:08:38

US3812293

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:53:22
User entered '28 Aug 2020'	Heather Cherniawski (b) (4)	28 Aug 2020 19:08:38

US3812293

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:53:22
User entered 'Clinic (Clinic)'	Heather Cherniawski (b) (4)	28 Aug 2020 19:08:38

US3812293

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	28 Aug 2020 19:08:38

US3812293

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:02:40
User entered '28 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 18:44:30

US3812293

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:20:44

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:02:40
User entered '109586'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 18:44:30

US3812293

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:02:40
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	28 Aug 2020 18:44:30

US3812293

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:20:44

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:02:40
User closed query 'PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4), (b) (6)	11 Sep 2020 09:53:38
Query 'PER CDM: Please complete this section of the form.' answered with 'UPDATED' (Site from DM).	Angie Kean (b) (4)	05 Sep 2020 23:28:43
User entered 'No (N)'	Angie Kean (b) (4)	05 Sep 2020 23:28:38
User opened query 'PER CDM: Please complete this section of the form.' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 07:34:24

US3812293

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:20:44

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:02:40
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:28:38

US3812293

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:02:40
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:28:38

US3812293

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:20:44

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:02:40
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:28:38

US3812293

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:20:44

[Liver Disease](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:02:40
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:28:38

US3812293

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 11:20:44

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:02:40
User entered 'No (N)'	Breanna Galibert (b) (4)	03 Oct 2020 18:16:37
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 09:49:07
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:30:41

US3812293

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:20:44

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:08:16
User entered missing code ND - Not Done.	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:30:51

US3812293

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:20:44

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:08:16
User entered missing code ND - Not Done.	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:30:51

US3812293

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:20:44

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:08:16
User entered missing code ND - Not Done.	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:30:51

US3812293

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:20:44

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:08:16
User entered missing code ND - Not Done.	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:30:51

US3812293

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:30:51

US3812293

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:08:16
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:30:51

US3812293

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:08:16
User entered '28 Aug 2020'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:30:51

US3812293

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:08:16
User entered '13:16'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:30:51

US3812293

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '28 Aug 2020 13:16'	System	05 Sep 2020 23:30:51

US3812293

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:08:16
User entered '98.2' F	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:30:51

US3812293

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:08:16
User entered 'Oral (Oral)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:30:51

US3812293

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:08:16
User entered empty.	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:30:51

US3812293

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:08:16
User entered '62'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:30:51

US3812293

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Sep 2020 23:30:51

US3812293

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:08:16
User entered '14'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:30:51

US3812293

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Sep 2020 23:30:51

US3812293

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:08:16
User entered '124'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:30:51

US3812293

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Sep 2020 23:30:51

US3812293

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:08:16
User entered '72'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:30:51

US3812293

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Sep 2020 23:30:51

US3812293

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:20:44

[Height](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:08:16
User entered missing code ND - Not Done.	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:30:51

US3812293

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 11:20:44

[Weight](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:08:16
User entered missing code ND - Not Done.	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:30:51

US3812293

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:30:51

US3812293

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:08:16
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:30:51

US3812293

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:08:16
User entered '28 Aug 2020'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:30:51

US3812293

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:08:16
User entered '14:30'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:30:51

US3812293

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '28 Aug 2020 14:30'	System	05 Sep 2020 23:30:51

US3812293

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:08:16
User entered '98.3' F	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:30:51

US3812293

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:08:16
User entered 'Oral (Oral)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:30:51

US3812293

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:08:16
User entered empty.	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:30:51

US3812293

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:08:16
User entered '59'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:30:51

US3812293

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Sep 2020 23:30:51

US3812293

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:08:16
User entered '16'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:30:51

US3812293

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Sep 2020 23:30:51

US3812293

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:08:16
User entered '120'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:30:51

US3812293

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Sep 2020 23:30:51

US3812293

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:08:16
User entered '75'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:30:51

US3812293

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Sep 2020 23:30:51

US3812293

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:20:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:08:39
User entered 'No (N)' reason for change: Data Entry Error	Karen Knapp (b) (4)	17 Sep 2020 00:22:00
User entered 'Yes (Y)'	Angie Kean (b) (4)	05 Sep 2020 23:28:50

US3812293

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 11:20:44

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:08:39
User entered empty; reason for change Data Entry Error	Karen Knapp (b) (4)	17 Sep 2020 00:22:00
User entered '28 Aug 2020'	(b) (4)	
	Angie Kean (b) (4)	05 Sep 2020 23:28:50
	(b) (4)	

US3812293

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:08:50
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	28 Aug 2020 19:09:34

US3812293

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

[If No, reason not given](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:08:50
User entered empty.	Heather Cherniawski (b) (4)	28 Aug 2020 19:09:34

US3812293

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:08:50
User entered empty.	Heather Cherniawski (b) (4)	28 Aug 2020 19:09:34

US3812293

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 19:09:34

US3812293

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:08:50
User entered '28 Aug 2020'	Heather Cherniawski (b) (4)	28 Aug 2020 19:09:34

US3812293

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:08:50
User entered '13:59'	Heather Cherniawski (b) (4)	28 Aug 2020 19:09:34

US3812293

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '28 Aug 2020 13:59'	System	28 Aug 2020 19:09:34

US3812293

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:08:50
User entered 'Right Arm (RIGHT ARM)'	Heather Cherniawski (b) (4)	28 Aug 2020 19:09:34

US3812293

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:08:50
User entered 'ONCE'	System	28 Aug 2020 19:09:34

US3812293

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 19:09:34

US3812293

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:09:34
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:31:04

US3812293

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:09:34
User entered '28 Aug 2020'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:31:04

US3812293

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:09:34
User entered '13:46'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:31:04

US3812293

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '28 Aug 2020 13:46'	System	05 Sep 2020 23:31:04

US3812293

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:20:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:09:41
User entered '28 Aug 2020'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:31:19

US3812293

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:20:44

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:31:19

US3812293

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:20:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:09:41
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:31:19

US3812293

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:20:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:09:41
User entered '13:51'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:31:19

US3812293

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '28 Aug 2020 13:51'	System	05 Sep 2020 23:31:19

US3812293

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:20:44

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:31:19

US3812293

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:20:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:09:41
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:31:19

US3812293

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:20:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:09:41
User entered empty.	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:31:19

US3812293

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	05 Sep 2020 23:31:19

US3812293

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:09:52
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:24:55

US3812293

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 23:24:55

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 19:09:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-28T14:21:16', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'eb3da3cc-b207-4291-bdb9-1881f4425705'	System	28 Aug 2020 19:21:47
User entered 'Yes (Y)'	System	28 Aug 2020 19:21:47

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-28T14:21:29', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'eb3da3cc-b207-4291-bdb9-1881f4425705'	System	28 Aug 2020 19:21:47
User entered '98.7'	System	28 Aug 2020 19:21:47

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-28T14:21:33', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'eb3da3cc-b207-4291-bdb9-1881f4425705'	System	28 Aug 2020 19:21:47
User entered 'No (N)'	System	28 Aug 2020 19:21:47

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-28T14:21:43', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'eb3da3cc-b207-4291-bdb9-1881f4425705'	System	28 Aug 2020 19:21:47
User entered '28 Aug 2020 14:21'	System	28 Aug 2020 19:21:47

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 14:19'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 16:49'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 19:09:34
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-28T18:23:12', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'd24371be-dd75-40d5-a739-b869fac394db'	System	28 Aug 2020 23:23:43
User entered 'Yes (Y)'	System	28 Aug 2020 23:23:43

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-28T18:23:25', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'd24371be-dd75-40d5-a739-b869fac394db'	System	28 Aug 2020 23:23:43
User entered '98.5'	System	28 Aug 2020 23:23:43

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-28T18:23:33', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'd24371be-dd75-40d5-a739-b869fac394db'	System	28 Aug 2020 23:23:43
User entered 'No (N)'	System	28 Aug 2020 23:23:43

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-28T18:23:41', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'd24371be-dd75-40d5-a739-b869fac394db'	System	28 Aug 2020 23:23:43
User entered '28 Aug 2020 18:23'	System	28 Aug 2020 23:23:43

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 17:44'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 19:09:34
User entered 'Day 2'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-29T12:00:37', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'f1cc4202-4121-4213-b48c-3c02c53a6750'	System	29 Aug 2020 17:01:03
User entered 'Yes (Y)'	System	29 Aug 2020 17:01:03

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-29T12:00:45', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'f1cc4202-4121-4213-b48c-3c02c53a6750'	System	29 Aug 2020 17:01:03
User entered '99.3'	System	29 Aug 2020 17:01:03

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-29T12:00:49', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'f1cc4202-4121-4213-b48c-3c02c53a6750'	System	29 Aug 2020 17:01:03
User entered 'No (N)'	System	29 Aug 2020 17:01:03

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-29T12:00:55', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'f1cc4202-4121-4213-b48c-3c02c53a6750'	System	29 Aug 2020 17:01:03
User entered '29 Aug 2020 12:00'	System	29 Aug 2020 17:01:03

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 19:09:34
User entered 'Day 3'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-30T13:08:49', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '87ae8078-e668-45c2-8951-3909a9f29710'	System	30 Aug 2020 18:09:19
User entered 'Yes (Y)'	System	30 Aug 2020 18:09:19

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-30T13:09:01', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '87ae8078-e668-45c2-8951-3909a9f29710'	System	30 Aug 2020 18:09:19
User entered '98.7'	System	30 Aug 2020 18:09:19

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-30T13:09:07', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '87ae8078-e668-45c2-8951-3909a9f29710'	System	30 Aug 2020 18:09:19
User entered 'No (N)'	System	30 Aug 2020 18:09:19

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-30T13:09:16', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '87ae8078-e668-45c2-8951-3909a9f29710'	System	30 Aug 2020 18:09:19
User entered '30 Aug 2020 13:09'	System	30 Aug 2020 18:09:19

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 19:09:34
User entered 'Day 4'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-31T13:29:04', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '7d9102f3-d5cb-4703-85c0-8d99f54d3503'	System	31 Aug 2020 18:30:24
User entered 'Yes (Y)'	System	31 Aug 2020 18:30:24

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-31T13:30:13', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '7d9102f3-d5cb-4703-85c0-8d99f54d3503'	System	31 Aug 2020 18:30:24
User entered '96.7'	System	31 Aug 2020 18:30:24

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-31T13:30:17', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '7d9102f3-d5cb-4703-85c0-8d99f54d3503'	System	31 Aug 2020 18:30:24
User entered 'No (N)'	System	31 Aug 2020 18:30:24

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-31T13:30:21', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '7d9102f3-d5cb-4703-85c0-8d99f54d3503'	System	31 Aug 2020 18:30:24
User entered '31 Aug 2020 13:30'	System	31 Aug 2020 18:30:24

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 19:09:34
User entered 'Day 5'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-01T12:02:29', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '5bc33d69-ecce-4200-b894-78cda5cf5ae5'	System	01 Sep 2020 17:02:54
User entered 'Yes (Y)'	System	01 Sep 2020 17:02:54

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-01T12:02:39', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '5bc33d69-ecce-4200-b894-78cda5cf5ae5'	System	01 Sep 2020 17:02:54
User entered '97.9'	System	01 Sep 2020 17:02:54

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-01T12:02:42', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '5bc33d69-ecce-4200-b894-78cda5cf5ae5'	System	01 Sep 2020 17:02:54
User entered 'No (N)'	System	01 Sep 2020 17:02:54

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-01T12:02:49', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '5bc33d69-ecce-4200-b894-78cda5cf5ae5'	System	01 Sep 2020 17:02:54
User entered '01 Sep 2020 12:02'	System	01 Sep 2020 17:02:54

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 19:09:34
User entered 'Day 6'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-02T13:10:52', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '99c1fe38-9f57-4a62-9e16-c2cb23e1f5a6'	System	02 Sep 2020 18:11:13
User entered 'Yes (Y)'	System	02 Sep 2020 18:11:13

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-02T13:10:59', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '99c1fe38-9f57-4a62-9e16-c2cb23e1f5a6'	System	02 Sep 2020 18:11:13
User entered '98.6'	System	02 Sep 2020 18:11:13

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-02T13:11:03', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '99c1fe38-9f57-4a62-9e16-c2cb23e1f5a6'	System	02 Sep 2020 18:11:13
User entered 'No (N)'	System	02 Sep 2020 18:11:13

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-02T13:11:09', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '99c1fe38-9f57-4a62-9e16-c2cb23e1f5a6'	System	02 Sep 2020 18:11:13
User entered '02 Sep 2020 13:11'	System	02 Sep 2020 18:11:13

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 19:09:34
User entered 'Day 7'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-03T12:11:34', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '6357d924-565c-404c-90b5-45460ccc1e48'	System	03 Sep 2020 17:11:47
User entered 'Yes (Y)'	System	03 Sep 2020 17:11:47

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-03T12:11:39', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '6357d924-565c-404c-90b5-45460ccc1e48'	System	03 Sep 2020 17:11:47
User entered '97.7'	System	03 Sep 2020 17:11:47

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-03T12:11:42', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '6357d924-565c-404c-90b5-45460ccc1e48'	System	03 Sep 2020 17:11:47
User entered 'No (N)'	System	03 Sep 2020 17:11:47

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-03T12:11:45', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '6357d924-565c-404c-90b5-45460ccc1e48'	System	03 Sep 2020 17:11:47
User entered '03 Sep 2020 12:11'	System	03 Sep 2020 17:11:47

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 19:09:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-28T14:21:58', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '128c37a2-0982-46a0-8c7a-bd4e38dfbb64'	System	28 Aug 2020 19:22:42
User entered 'None (1)'	System	28 Aug 2020 19:22:42

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-28T14:22:23', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '128c37a2-0982-46a0-8c7a-bd4e38dfbb64'	System	28 Aug 2020 19:22:42
User entered 'No (N)'	System	28 Aug 2020 19:22:42

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-28T14:22:27', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '128c37a2-0982-46a0-8c7a-bd4e38dfbb64'	System	28 Aug 2020 19:22:42
User entered 'No (N)'	System	28 Aug 2020 19:22:42

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-28T14:22:33', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '128c37a2-0982-46a0-8c7a-bd4e38dfbb64'	System	28 Aug 2020 19:22:42
User entered 'None (1)'	System	28 Aug 2020 19:22:42

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-28T14:22:39', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '128c37a2-0982-46a0-8c7a-bd4e38dfbb64'	System	28 Aug 2020 19:22:42
User entered '28 Aug 2020 14:22'	System	28 Aug 2020 19:22:42

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 14:19'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 16:49'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 19:09:34
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-28T18:23:51', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '8b135062-e1b5-4419-81a7-f49893fa12aa'	System	28 Aug 2020 23:24:22
User entered 'Does not interfere with activity (2)'	System	28 Aug 2020 23:24:22

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-28T18:24:03', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '8b135062-e1b5-4419-81a7-f49893fa12aa'	System	28 Aug 2020 23:24:22
User entered 'No (N)'	System	28 Aug 2020 23:24:22

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-28T18:24:06', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '8b135062-e1b5-4419-81a7-f49893fa12aa'	System	28 Aug 2020 23:24:22
User entered 'No (N)'	System	28 Aug 2020 23:24:22

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-28T18:24:13', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '8b135062-e1b5-4419-81a7-f49893fa12aa'	System	28 Aug 2020 23:24:22
User entered 'None (1)'	System	28 Aug 2020 23:24:22

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-28T18:24:20', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '8b135062-e1b5-4419-81a7-f49893fa12aa'	System	28 Aug 2020 23:24:22
User entered '28 Aug 2020 18:24'	System	28 Aug 2020 23:24:22

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 17:44'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 19:09:34
User entered 'Day 2'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-29T12:01:07', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '130e2b1d-4d76-4299-b7fc-bb9b6638b455'	System	29 Aug 2020 17:01:49
User entered 'Does not interfere with activity (2)'	System	29 Aug 2020 17:01:49

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-29T12:01:20', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '130e2b1d-4d76-4299-b7fc-bb9b6638b455'	System	29 Aug 2020 17:01:49
User entered 'No (N)'	System	29 Aug 2020 17:01:49

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-29T12:01:34', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '130e2b1d-4d76-4299-b7fc-bb9b6638b455'	System	29 Aug 2020 17:01:49
User entered 'No (N)'	System	29 Aug 2020 17:01:49

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-29T12:01:39', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '130e2b1d-4d76-4299-b7fc-bb9b6638b455'	System	29 Aug 2020 17:01:49
User entered 'None (1)'	System	29 Aug 2020 17:01:49

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-29T12:01:45', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '130e2b1d-4d76-4299-b7fc-bb9b6638b455'	System	29 Aug 2020 17:01:49
User entered '29 Aug 2020 12:01'	System	29 Aug 2020 17:01:49

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 19:09:34
User entered 'Day 3'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-30T13:09:23', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '030047c4-0c87-4554-9672-c81f27984f20'	System	30 Aug 2020 18:09:40
User entered 'Does not interfere with activity (2)'	System	30 Aug 2020 18:09:40

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-30T13:09:26', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '030047c4-0c87-4554-9672-c81f27984f20'	System	30 Aug 2020 18:09:40
User entered 'No (N)'	System	30 Aug 2020 18:09:40

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-30T13:09:30', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '030047c4-0c87-4554-9672-c81f27984f20'	System	30 Aug 2020 18:09:40
User entered 'No (N)'	System	30 Aug 2020 18:09:40

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-30T13:09:33', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '030047c4-0c87-4554-9672-c81f27984f20'	System	30 Aug 2020 18:09:40
User entered 'None (1)'	System	30 Aug 2020 18:09:40

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-30T13:09:37', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '030047c4-0c87-4554-9672-c81f27984f20'	System	30 Aug 2020 18:09:40
User entered '30 Aug 2020 13:09'	System	30 Aug 2020 18:09:40

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 19:09:34
User entered 'Day 4'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-31T13:30:26', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '5beb2dc0-11c2-4c40-bcdc-11d4d69393c2'	System	31 Aug 2020 18:30:48
User entered 'None (1)'	System	31 Aug 2020 18:30:48

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-31T13:30:29', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '5beb2dc0-11c2-4c40-bcdc-11d4d69393c2'	System	31 Aug 2020 18:30:48
User entered 'No (N)'	System	31 Aug 2020 18:30:48

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-31T13:30:32', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '5beb2dc0-11c2-4c40-bcdc-11d4d69393c2'	System	31 Aug 2020 18:30:48
User entered 'No (N)'	System	31 Aug 2020 18:30:48

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-31T13:30:40', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '5beb2dc0-11c2-4c40-bcdc-11d4d69393c2'	System	31 Aug 2020 18:30:48
User entered 'None (1)'	System	31 Aug 2020 18:30:48

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-31T13:30:44', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '5beb2dc0-11c2-4c40-bcdc-11d4d69393c2'	System	31 Aug 2020 18:30:48
User entered '31 Aug 2020 13:30'	System	31 Aug 2020 18:30:48

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 19:09:34
User entered 'Day 5'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-01T12:02:55', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'a779d890-e70b-4d97-9929-6a04c15c6818'	System	01 Sep 2020 17:03:12
User entered 'None (1)'	System	01 Sep 2020 17:03:12

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-01T12:02:57', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'a779d890-e70b-4d97-9929-6a04c15c6818'	System	01 Sep 2020 17:03:12
User entered 'No (N)'	System	01 Sep 2020 17:03:12

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-01T12:03:00', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'a779d890-e70b-4d97-9929-6a04c15c6818'	System	01 Sep 2020 17:03:12
User entered 'No (N)'	System	01 Sep 2020 17:03:12

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-01T12:03:04', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'a779d890-e70b-4d97-9929-6a04c15c6818'	System	01 Sep 2020 17:03:12
User entered 'None (1)'	System	01 Sep 2020 17:03:12

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-01T12:03:08', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'a779d890-e70b-4d97-9929-6a04c15c6818'	System	01 Sep 2020 17:03:12
User entered '01 Sep 2020 12:03'	System	01 Sep 2020 17:03:12

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 19:09:34
User entered 'Day 6'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-02T13:11:16', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'b195e19a-3a4e-4c2a-8c54-0f5ef2b4ad69'	System	02 Sep 2020 18:11:28
User entered 'None (1)'	System	02 Sep 2020 18:11:28

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-02T13:11:18', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'b195e19a-3a4e-4c2a-8c54-0f5ef2b4ad69'	System	02 Sep 2020 18:11:28
User entered 'No (N)'	System	02 Sep 2020 18:11:28

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-02T13:11:20', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'b195e19a-3a4e-4c2a-8c54-0f5ef2b4ad69'	System	02 Sep 2020 18:11:28
User entered 'No (N)'	System	02 Sep 2020 18:11:28

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-02T13:11:23', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'b195e19a-3a4e-4c2a-8c54-0f5ef2b4ad69'	System	02 Sep 2020 18:11:28
User entered 'None (1)'	System	02 Sep 2020 18:11:28

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-02T13:11:26', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'b195e19a-3a4e-4c2a-8c54-0f5ef2b4ad69'	System	02 Sep 2020 18:11:28
User entered '02 Sep 2020 13:11'	System	02 Sep 2020 18:11:28

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 19:09:34
User entered 'Day 7'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-03T12:11:51', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '251ad123-e641-49d4-9981-7abd7a3b4c9b'	System	03 Sep 2020 17:12:25
User entered 'None (1)'	System	03 Sep 2020 17:12:25

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-03T12:11:55', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '251ad123-e641-49d4-9981-7abd7a3b4c9b'	System	03 Sep 2020 17:12:25
User entered 'No (N)'	System	03 Sep 2020 17:12:25

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-03T12:12:13', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '251ad123-e641-49d4-9981-7abd7a3b4c9b'	System	03 Sep 2020 17:12:25
User entered 'No (N)'	System	03 Sep 2020 17:12:25

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

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

Please select one response below

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-03T12:12:18', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '251ad123-e641-49d4-9981-7abd7a3b4c9b'	System	03 Sep 2020 17:12:25
User entered 'None (1)'	System	03 Sep 2020 17:12:25

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-03T12:12:21', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '251ad123-e641-49d4-9981-7abd7a3b4c9b'	System	03 Sep 2020 17:12:25
User entered '03 Sep 2020 12:12'	System	03 Sep 2020 17:12:25

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 19:09:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-28T14:22:47', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '8a090ffa-9661-4bcc-b929-7bcfbc9e8e34'	System	28 Aug 2020 19:23:39
User entered 'None (0)'	System	28 Aug 2020 19:23:39

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-28T14:22:51', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '8a090ffa-9661-4bcc-b929-7bcfbc9e8e34'	System	28 Aug 2020 19:23:39
User entered 'None (0)'	System	28 Aug 2020 19:23:39

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-28T14:22:54', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '8a090ffa-9661-4bcc-b929-7bcfbc9e8e34'	System	28 Aug 2020 19:23:39
User entered 'None (0)'	System	28 Aug 2020 19:23:39

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-28T14:22:58', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '8a090ffa-9661-4bcc-b929-7bcfbc9e8e34'	System	28 Aug 2020 19:23:39
User entered 'None (0)'	System	28 Aug 2020 19:23:39

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-28T14:23:19', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '8a090ffa-9661-4bcc-b929-7bcfbc9e8e34'	System	28 Aug 2020 19:23:39
User entered 'None (0)'	System	28 Aug 2020 19:23:39

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-28T14:23:21', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '8a090ffa-9661-4bcc-b929-7bcfbc9e8e34'	System	28 Aug 2020 19:23:39
User entered 'None (0)'	System	28 Aug 2020 19:23:39

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-28T14:23:29', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '8a090ffa-9661-4bcc-b929-7bcfbc9e8e34'	System	28 Aug 2020 19:23:39
User entered 'No (N)'	System	28 Aug 2020 19:23:39

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-28T14:23:34', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '8a090ffa-9661-4bcc-b929-7bcfbc9e8e34'	System	28 Aug 2020 19:23:39
User entered '28 Aug 2020 14:23'	System	28 Aug 2020 19:23:39

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 14:19'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 16:49'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 19:09:34
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-28T18:24:26', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '85ae3659-9344-40b8-8d46-eee1a24fc7ad'	System	28 Aug 2020 23:24:53
User entered 'None (0)'	System	28 Aug 2020 23:24:53

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-28T18:24:28', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '85ae3659-9344-40b8-8d46-eee1a24fc7ad'	System	28 Aug 2020 23:24:53
User entered 'None (0)'	System	28 Aug 2020 23:24:53

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-28T18:24:31', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '85ae3659-9344-40b8-8d46-eee1a24fc7ad'	System	28 Aug 2020 23:24:53
User entered 'None (0)'	System	28 Aug 2020 23:24:53

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-28T18:24:33', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '85ae3659-9344-40b8-8d46-eee1a24fc7ad'	System	28 Aug 2020 23:24:53
User entered 'None (0)'	System	28 Aug 2020 23:24:53

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-28T18:24:36', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '85ae3659-9344-40b8-8d46-eee1a24fc7ad'	System	28 Aug 2020 23:24:53
User entered 'None (0)'	System	28 Aug 2020 23:24:53

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-28T18:24:38', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '85ae3659-9344-40b8-8d46-eee1a24fc7ad'	System	28 Aug 2020 23:24:53
User entered 'None (0)'	System	28 Aug 2020 23:24:53

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-28T18:24:46', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '85ae3659-9344-40b8-8d46-eee1a24fc7ad'	System	28 Aug 2020 23:24:53
User entered 'No (N)'	System	28 Aug 2020 23:24:53

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-28T18:24:50', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '85ae3659-9344-40b8-8d46-eee1a24fc7ad'	System	28 Aug 2020 23:24:53
User entered '28 Aug 2020 18:24'	System	28 Aug 2020 23:24:53

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 17:44'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 19:09:34
User entered 'Day 2'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-29T12:01:51', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'f0af52e3-6f4f-4fb5-88a7-77ef3eec9352'	System	29 Aug 2020 17:02:23
User entered 'None (0)'	System	29 Aug 2020 17:02:23

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-29T12:01:57', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'f0af52e3-6f4f-4fb5-88a7-77ef3eec9352'	System	29 Aug 2020 17:02:23
User entered 'No interference with activity (1)'	System	29 Aug 2020 17:02:23

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-29T12:02:02', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'f0af52e3-6f4f-4fb5-88a7-77ef3eec9352'	System	29 Aug 2020 17:02:23
User entered 'None (0)'	System	29 Aug 2020 17:02:23

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-29T12:02:06', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'f0af52e3-6f4f-4fb5-88a7-77ef3eec9352'	System	29 Aug 2020 17:02:23
User entered 'None (0)'	System	29 Aug 2020 17:02:23

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-29T12:02:09', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'f0af52e3-6f4f-4fb5-88a7-77ef3eec9352'	System	29 Aug 2020 17:02:23
User entered 'None (0)'	System	29 Aug 2020 17:02:23

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-29T12:02:12', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'f0af52e3-6f4f-4fb5-88a7-77ef3eec9352'	System	29 Aug 2020 17:02:23
User entered 'None (0)'	System	29 Aug 2020 17:02:23

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-29T12:02:16', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'f0af52e3-6f4f-4fb5-88a7-77ef3eec9352'	System	29 Aug 2020 17:02:23
User entered 'No (N)'	System	29 Aug 2020 17:02:23

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-29T12:02:19', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'f0af52e3-6f4f-4fb5-88a7-77ef3eec9352'	System	29 Aug 2020 17:02:23
User entered '29 Aug 2020 12:02'	System	29 Aug 2020 17:02:23

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 19:09:34
User entered 'Day 3'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-30T13:10:14', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '23051ede-1177-43b2-a4fe-a8cdd63b7c35'	System	30 Aug 2020 18:11:13
User entered 'None (0)'	System	30 Aug 2020 18:11:13

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-30T13:10:19', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '23051ede-1177-43b2-a4fe-a8cdd63b7c35'	System	30 Aug 2020 18:11:13
User entered 'None (0)'	System	30 Aug 2020 18:11:13

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-30T13:10:22', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '23051ede-1177-43b2-a4fe-a8cdd63b7c35'	System	30 Aug 2020 18:11:13
User entered 'None (0)'	System	30 Aug 2020 18:11:13

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-30T13:10:25', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '23051ede-1177-43b2-a4fe-a8cdd63b7c35'	System	30 Aug 2020 18:11:13
User entered 'None (0)'	System	30 Aug 2020 18:11:13

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-30T13:10:28', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '23051ede-1177-43b2-a4fe-a8cdd63b7c35'	System	30 Aug 2020 18:11:13
User entered 'None (0)'	System	30 Aug 2020 18:11:13

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-30T13:10:41', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '23051ede-1177-43b2-a4fe-a8cdd63b7c35'	System	30 Aug 2020 18:11:13
User entered 'None (0)'	System	30 Aug 2020 18:11:13

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-30T13:11:04', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '23051ede-1177-43b2-a4fe-a8cdd63b7c35'	System	30 Aug 2020 18:11:13
User entered 'No (N)'	System	30 Aug 2020 18:11:13

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-30T13:11:08', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '23051ede-1177-43b2-a4fe-a8cdd63b7c35'	System	30 Aug 2020 18:11:13
User entered '30 Aug 2020 13:11'	System	30 Aug 2020 18:11:13

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 19:09:34
User entered 'Day 4'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-31T13:30:55', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'e9301ef0-e97f-4dea-9cfb-28ee1d8493e3'	System	31 Aug 2020 18:31:34
User entered 'None (0)'	System	31 Aug 2020 18:31:34

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-31T13:31:03', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'e9301ef0-e97f-4dea-9cfb-28ee1d8493e3'	System	31 Aug 2020 18:31:34
User entered 'No interference with activity (1)'	System	31 Aug 2020 18:31:34

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-31T13:31:06', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'e9301ef0-e97f-4dea-9cfb-28ee1d8493e3'	System	31 Aug 2020 18:31:34
User entered 'None (0)'	System	31 Aug 2020 18:31:34

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-31T13:31:13', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'e9301ef0-e97f-4dea-9cfb-28ee1d8493e3'	System	31 Aug 2020 18:31:34
User entered 'None (0)'	System	31 Aug 2020 18:31:34

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-31T13:31:16', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'e9301ef0-e97f-4dea-9cfb-28ee1d8493e3'	System	31 Aug 2020 18:31:34
User entered 'None (0)'	System	31 Aug 2020 18:31:34

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-31T13:31:19', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'e9301ef0-e97f-4dea-9cfb-28ee1d8493e3'	System	31 Aug 2020 18:31:34
User entered 'None (0)'	System	31 Aug 2020 18:31:34

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-31T13:31:27', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'e9301ef0-e97f-4dea-9cfb-28ee1d8493e3'	System	31 Aug 2020 18:31:34
User entered 'No (N)'	System	31 Aug 2020 18:31:34

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-08-31T13:31:32', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'e9301ef0-e97f-4dea-9cfb-28ee1d8493e3'	System	31 Aug 2020 18:31:34
User entered '31 Aug 2020 13:31'	System	31 Aug 2020 18:31:34

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 19:09:34
User entered 'Day 5'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-01T12:03:15', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '74acc40b-87b1-4fa2-a0d0-06b534aae42d'	System	01 Sep 2020 17:04:11
User entered 'None (0)'	System	01 Sep 2020 17:04:11

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-01T12:03:18', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '74acc40b-87b1-4fa2-a0d0-06b534aae42d'	System	01 Sep 2020 17:04:11
User entered 'No interference with activity (1)'	System	01 Sep 2020 17:04:11

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-01T12:04:01', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '74acc40b-87b1-4fa2-a0d0-06b534aae42d'	System	01 Sep 2020 17:04:11
User entered 'None (0)'	System	01 Sep 2020 17:04:11

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-01T12:03:29', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '74acc40b-87b1-4fa2-a0d0-06b534aae42d'	System	01 Sep 2020 17:04:11
User entered 'No interference with activity (1)'	System	01 Sep 2020 17:04:11

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-01T12:03:40', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '74acc40b-87b1-4fa2-a0d0-06b534aae42d'	System	01 Sep 2020 17:04:11
User entered 'None (0)'	System	01 Sep 2020 17:04:11

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-01T12:03:46', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '74acc40b-87b1-4fa2-a0d0-06b534aae42d'	System	01 Sep 2020 17:04:11
User entered 'None (0)'	System	01 Sep 2020 17:04:11

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-01T12:03:58', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '74acc40b-87b1-4fa2-a0d0-06b534aae42d'	System	01 Sep 2020 17:04:11
User entered 'No (N)'	System	01 Sep 2020 17:04:11

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-01T12:04:06', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '74acc40b-87b1-4fa2-a0d0-06b534aae42d'	System	01 Sep 2020 17:04:11
User entered '01 Sep 2020 12:04'	System	01 Sep 2020 17:04:11

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 19:09:34
User entered 'Day 6'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-02T13:11:31', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '244033c7-b202-46e8-b872-3a318a6562cf'	System	02 Sep 2020 18:12:18
User entered 'None (0)'	System	02 Sep 2020 18:12:18

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-02T13:11:37', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '244033c7-b202-46e8-b872-3a318a6562cf'	System	02 Sep 2020 18:12:18
User entered 'No interference with activity (1)'	System	02 Sep 2020 18:12:18

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-02T13:11:39', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '244033c7-b202-46e8-b872-3a318a6562cf'	System	02 Sep 2020 18:12:18
User entered 'None (0)'	System	02 Sep 2020 18:12:18

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-02T13:11:42', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '244033c7-b202-46e8-b872-3a318a6562cf'	System	02 Sep 2020 18:12:18
User entered 'None (0)'	System	02 Sep 2020 18:12:18

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-02T13:11:45', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '244033c7-b202-46e8-b872-3a318a6562cf'	System	02 Sep 2020 18:12:18
User entered 'None (0)'	System	02 Sep 2020 18:12:18

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-02T13:11:47', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '244033c7-b202-46e8-b872-3a318a6562cf'	System	02 Sep 2020 18:12:18
User entered 'None (0)'	System	02 Sep 2020 18:12:18

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-02T13:12:11', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '244033c7-b202-46e8-b872-3a318a6562cf'	System	02 Sep 2020 18:12:18
User entered 'No (N)'	System	02 Sep 2020 18:12:18

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-02T13:12:15', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '244033c7-b202-46e8-b872-3a318a6562cf'	System	02 Sep 2020 18:12:18
User entered '02 Sep 2020 13:12'	System	02 Sep 2020 18:12:18

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 19:09:34
User entered 'Day 7'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-03T12:12:27', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'c86ea1e1-2d8e-41f0-b294-0ff52122e3fa'	System	03 Sep 2020 17:12:59
User entered 'None (0)'	System	03 Sep 2020 17:12:59

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-03T12:12:33', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'c86ea1e1-2d8e-41f0-b294-0ff52122e3fa'	System	03 Sep 2020 17:12:59
User entered 'No interference with activity (1)'	System	03 Sep 2020 17:12:59

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-03T12:12:38', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'c86ea1e1-2d8e-41f0-b294-0ff52122e3fa'	System	03 Sep 2020 17:12:59
User entered 'None (0)'	System	03 Sep 2020 17:12:59

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-03T12:12:40', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'c86ea1e1-2d8e-41f0-b294-0ff52122e3fa'	System	03 Sep 2020 17:12:59
User entered 'None (0)'	System	03 Sep 2020 17:12:59

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-03T12:12:42', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'c86ea1e1-2d8e-41f0-b294-0ff52122e3fa'	System	03 Sep 2020 17:12:59
User entered 'None (0)'	System	03 Sep 2020 17:12:59

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-03T12:12:45', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'c86ea1e1-2d8e-41f0-b294-0ff52122e3fa'	System	03 Sep 2020 17:12:59
User entered 'None (0)'	System	03 Sep 2020 17:12:59

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-03T12:12:53', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'c86ea1e1-2d8e-41f0-b294-0ff52122e3fa'	System	03 Sep 2020 17:12:59
User entered 'No (N)'	System	03 Sep 2020 17:12:59

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-03T12:12:56', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'c86ea1e1-2d8e-41f0-b294-0ff52122e3fa'	System	03 Sep 2020 17:12:59
User entered '03 Sep 2020 12:12'	System	03 Sep 2020 17:12:59

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 19:09:34

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 18:12:18
User entered 'Day 8'	System	02 Sep 2020 18:12:18

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-04T17:55:42', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '7e83017c-eaa4-4a13-b007-ce21ee18cd6f'	System	04 Sep 2020 22:55:53
User entered 'No interference with activity (1)'	System	04 Sep 2020 22:55:53

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-04T17:55:46', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '7e83017c-eaa4-4a13-b007-ce21ee18cd6f'	System	04 Sep 2020 22:55:53
User entered '04 Sep 2020 17:55'	System	04 Sep 2020 22:55:53

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 18:12:18

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 18:12:18

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 11:20:44

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 17:12:59
User entered 'Day 9'	System	03 Sep 2020 17:12:59

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-05T12:11:51', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '4d786374-fa7b-4c17-b261-480fbefead4f'	System	05 Sep 2020 17:12:02
User entered 'No interference with activity (1)'	System	05 Sep 2020 17:12:02

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-05T12:11:55', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '4d786374-fa7b-4c17-b261-480fbefead4f'	System	05 Sep 2020 17:12:02
User entered '05 Sep 2020 12:11'	System	05 Sep 2020 17:12:02

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 17:12:59

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 17:12:59

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 22:55:53
User entered 'Day 10'	System	04 Sep 2020 22:55:53

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-06T13:07:36', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '1b7b5a4a-5632-431f-8182-e1122efda6af'	System	06 Sep 2020 18:07:46
User entered 'No interference with activity (1)'	System	06 Sep 2020 18:07:46

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-06T13:07:40', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '1b7b5a4a-5632-431f-8182-e1122efda6af'	System	06 Sep 2020 18:07:46
User entered '06 Sep 2020 13:07'	System	06 Sep 2020 18:07:46

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 22:55:53

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 22:55:53

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Sep 2020 17:12:02
User entered 'Day 11'	System	05 Sep 2020 17:12:02

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-07T12:03:38', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'feb56c79-7c0b-4574-b262-ecf9d3a26845'	System	07 Sep 2020 17:03:48
User entered 'No interference with activity (1)'	System	07 Sep 2020 17:03:48

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-07T12:03:41', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'feb56c79-7c0b-4574-b262-ecf9d3a26845'	System	07 Sep 2020 17:03:48
User entered '07 Sep 2020 12:03'	System	07 Sep 2020 17:03:48

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 17:12:02

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 17:12:02

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 26 Nov 2020 11:20:44

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	06 Sep 2020 18:07:46
User entered 'Day 12'	System	06 Sep 2020 18:07:46

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-08T16:29:17', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '415312f7-4839-4d7e-b663-39f464d34ab8'	System	08 Sep 2020 21:29:29
User entered 'No interference with activity (1)'	System	08 Sep 2020 21:29:29

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-08T16:29:22', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '415312f7-4839-4d7e-b663-39f464d34ab8'	System	08 Sep 2020 21:29:29
User entered '08 Sep 2020 16:29'	System	08 Sep 2020 21:29:29

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	06 Sep 2020 18:07:46

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(12)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	06 Sep 2020 18:07:46

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Sep 2020 17:03:48
User entered 'Day 13'	System	07 Sep 2020 17:03:48

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-09T12:00:45', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '6186f66c-8885-4789-9a61-24231390465c'	System	09 Sep 2020 17:02:12
User entered 'No interference with activity (1)'	System	09 Sep 2020 17:02:12

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-09T12:00:49', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '6186f66c-8885-4789-9a61-24231390465c'	System	09 Sep 2020 17:02:12
User entered '09 Sep 2020 12:00'	System	09 Sep 2020 17:02:12

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 17:03:48

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(13)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 17:03:48

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 21:29:29
User entered 'Day 14'	System	08 Sep 2020 21:29:29

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-10T14:55:40', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '16fde553-cf4e-43d5-8547-0abe60856951'	System	10 Sep 2020 19:55:52
User entered 'No interference with activity (1)'	System	10 Sep 2020 19:55:52

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-10T14:55:43', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '16fde553-cf4e-43d5-8547-0abe60856951'	System	10 Sep 2020 19:55:52
User entered '10 Sep 2020 14:55'	System	10 Sep 2020 19:55:52

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 21:29:29

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(14)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 21:29:29

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 26 Nov 2020 11:20:44

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 17:02:12
User entered 'Day 15'	System	09 Sep 2020 17:02:12

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-11T12:11:46', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '2de02bc7-2fef-4585-9ec0-8ccf473c164d'	System	11 Sep 2020 17:12:10
User entered 'No interference with activity (1)'	System	11 Sep 2020 17:12:10

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-11T12:11:49', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '2de02bc7-2fef-4585-9ec0-8ccf473c164d'	System	11 Sep 2020 17:12:10
User entered '11 Sep 2020 12:11'	System	11 Sep 2020 17:12:10

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 17:02:12

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(15)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 17:02:12

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 19:55:52
User entered 'Day 16'	System	10 Sep 2020 19:55:52

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-12T12:12:51', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '1ad39350-1528-4142-8187-134e15440b55'	System	12 Sep 2020 17:13:02
User entered 'None (0)'	System	12 Sep 2020 17:13:02

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 26 Nov 2020 11:20:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-12T12:12:54', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '1ad39350-1528-4142-8187-134e15440b55'	System	12 Sep 2020 17:13:02
User entered '12 Sep 2020 12:12'	System	12 Sep 2020 17:13:02

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 19:55:52

US3812293

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(16)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 19:55:52

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 18:12:18
User entered 'Day 8'	System	02 Sep 2020 18:12:18

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-04T17:55:54', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'be6a147f-afa4-4353-b4e5-e19c78fd2842'	System	04 Sep 2020 22:56:07
User entered 'No (N)'	System	04 Sep 2020 22:56:07

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-04T17:55:58', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'be6a147f-afa4-4353-b4e5-e19c78fd2842'	System	04 Sep 2020 22:56:07
User entered '04 Sep 2020 17:55'	System	04 Sep 2020 22:56:07

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 18:12:18

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 18:12:18

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 17:12:59
User entered 'Day 9'	System	03 Sep 2020 17:12:59

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-05T12:12:01', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '41585611-2e6e-4855-95b7-67aa67e2d694'	System	05 Sep 2020 17:12:12
User entered 'No (N)'	System	05 Sep 2020 17:12:12

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-05T12:12:04', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '41585611-2e6e-4855-95b7-67aa67e2d694'	System	05 Sep 2020 17:12:12
User entered '05 Sep 2020 12:12'	System	05 Sep 2020 17:12:12

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 17:12:59

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 17:12:59

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Sep 2020 22:55:53
User entered 'Day 10'	System	04 Sep 2020 22:55:53

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-06T13:07:44', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '7ccde8c0-24a6-44bd-9b03-3ec54df4c501'	System	06 Sep 2020 18:07:55
User entered 'No (N)'	System	06 Sep 2020 18:07:55

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-06T13:07:47', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '7ccde8c0-24a6-44bd-9b03-3ec54df4c501'	System	06 Sep 2020 18:07:55
User entered '06 Sep 2020 13:07'	System	06 Sep 2020 18:07:55

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 22:55:53

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 22:55:53

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Sep 2020 17:12:02
User entered 'Day 11'	System	05 Sep 2020 17:12:02

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-07T12:03:45', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '12761bdc-f3ee-4fdd-9cb4-d280a543b527'	System	07 Sep 2020 17:03:54
User entered 'No (N)'	System	07 Sep 2020 17:03:54

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-07T12:03:48', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '12761bdc-f3ee-4fdd-9cb4-d280a543b527'	System	07 Sep 2020 17:03:54
User entered '07 Sep 2020 12:03'	System	07 Sep 2020 17:03:54

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Sep 2020 12:00'	System	05 Sep 2020 17:12:02

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 11:59'	System	05 Sep 2020 17:12:02

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	06 Sep 2020 18:07:46
User entered 'Day 12'	System	06 Sep 2020 18:07:46

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-08T16:29:33', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'e8180218-8358-45e5-8ef8-d346edda0747'	System	08 Sep 2020 21:29:51
User entered 'Yes (Y)'	System	08 Sep 2020 21:29:51

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-08T16:29:43', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'e8180218-8358-45e5-8ef8-d346edda0747'	System	08 Sep 2020 21:29:51
User entered '08 Sep 2020 16:29'	System	08 Sep 2020 21:29:51

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Sep 2020 12:00'	System	06 Sep 2020 18:07:46

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 11:59'	System	06 Sep 2020 18:07:46

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	07 Sep 2020 17:03:48
User entered 'Day 13'	System	07 Sep 2020 17:03:48

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-09T12:01:01', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '6a2b8d65-d4bd-4ad4-9d35-ef5f20fb5273'	System	09 Sep 2020 17:02:17
User entered 'Yes (Y)'	System	09 Sep 2020 17:02:17

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-09T12:01:05', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '6a2b8d65-d4bd-4ad4-9d35-ef5f20fb5273'	System	09 Sep 2020 17:02:17
User entered '09 Sep 2020 12:01'	System	09 Sep 2020 17:02:17

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 17:03:48

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 17:03:48

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Sep 2020 21:29:29
User entered 'Day 14'	System	08 Sep 2020 21:29:29

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-10T14:55:28', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '27f48328-6ddb-4089-b91e-32fbe2fc85cf'	System	10 Sep 2020 19:55:41
User entered 'No (N)'	System	10 Sep 2020 19:55:41

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-10T14:55:34', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '27f48328-6ddb-4089-b91e-32fbe2fc85cf'	System	10 Sep 2020 19:55:41
User entered '10 Sep 2020 14:55'	System	10 Sep 2020 19:55:41

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 21:29:29

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 21:29:29

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	09 Sep 2020 17:02:12
User entered 'Day 15'	System	09 Sep 2020 17:02:12

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-11T12:11:35', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '8e5be623-28e8-4124-b4af-500fba03f0e4'	System	11 Sep 2020 17:11:59
User entered 'No (N)'	System	11 Sep 2020 17:11:59

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-11T12:11:38', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '8e5be623-28e8-4124-b4af-500fba03f0e4'	System	11 Sep 2020 17:11:59
User entered '11 Sep 2020 12:11'	System	11 Sep 2020 17:11:59

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 17:02:12

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 17:02:12

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 19:55:52
User entered 'Day 16'	System	10 Sep 2020 19:55:52

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-12T12:12:42', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'ab2b1e65-77bb-4fc0-b14e-7410dc374d49'	System	12 Sep 2020 17:12:56
User entered 'No (N)'	System	12 Sep 2020 17:12:56

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 11:20:44

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-09-12T12:12:46', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'ab2b1e65-77bb-4fc0-b14e-7410dc374d49'	System	12 Sep 2020 17:12:56
User entered '12 Sep 2020 12:12'	System	12 Sep 2020 17:12:56

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 11:20:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 19:55:52

US3812293

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 11:20:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 19:55:52

US3812293

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:10:30
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:25:05

US3812293

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Un-verified.	Karen Knapp (b) (4) (b) (4)	10 Nov 2020 23:12:32
User entered '04 Sep 2020' reason for change: Per Query Resolution	Karen Knapp (b) (4) (b) (4)	10 Nov 2020 23:12:32
DataPoint Verified.	(b) (4), (b) (6) (b) (4)	05 Oct 2020 20:10:30
User entered '4 Sep 2020'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:25:05

US3812293

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:10:30
User entered 'Contact Made (CONTACT MADE)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:25:05

US3812293

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:10:30
User entered empty.	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:25:05

US3812293

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:10:42
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	11 Sep 2020 18:56:43

US3812293

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 18:56:43

US3812293

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:18:49
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	11 Sep 2020 18:56:55

US3812293

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:18:49
User entered '11 Sep 2020'	Karen Knapp (b) (4) (b) (4)	11 Sep 2020 18:56:55

US3812293

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:18:49
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4) (b) (4)	11 Sep 2020 18:56:55

US3812293

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:18:49
User entered empty.	Karen Knapp (b) (4) (b) (4)	11 Sep 2020 18:56:55

US3812293

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:19:01
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	11 Sep 2020 18:57:02

US3812293

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 18:57:02

US3812293

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:19:27
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	18 Sep 2020 15:40:02

US3812293

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:19:27
User entered '18 Sep 2020'	Karen Knapp (b) (4) (b) (4)	18 Sep 2020 15:40:02

US3812293

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:19:27
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4) (b) (4)	18 Sep 2020 15:40:02

US3812293

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:19:27
User entered empty.	Karen Knapp (b) (4) (b) (4)	18 Sep 2020 15:40:02

US3812293

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:19:36
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	18 Sep 2020 15:40:07

US3812293

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Sep 2020 15:40:07

US3812293

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:20:18
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 19:09:26

US3812293

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:20:18
User entered '28 Sep 2020'	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 19:09:26

US3812293

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:20:18
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 19:09:26

US3812293

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	28 Sep 2020 19:09:26

US3812293

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Breanna Galibert (b) (4)	30 Sep 2020 16:04:47
	(b) (4)	

US3812293

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:27:58
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:04:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:27:58
User entered '28 Sep 2020'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:04:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:27:58
User entered '13:56'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:04:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '28 Sep 2020 13:56'	System	30 Sep 2020 16:04:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:27:58
User entered '96.8' F	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:04:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:27:58
User entered 'Oral (Oral)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:04:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:27:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:04:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:27:58
User entered '61'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:04:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	30 Sep 2020 16:04:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:27:58
User entered '14'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:04:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	30 Sep 2020 16:04:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:27:58
User entered '126'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:04:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Sep 2020 16:04:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:27:58
User entered '70'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:04:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 11:20:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	30 Sep 2020 16:04:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:04:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:27:58
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:04:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:27:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:04:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:27:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:04:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 16:04:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:27:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:04:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:27:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:04:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:27:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:04:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:27:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:04:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 16:04:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:27:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:04:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 16:04:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:27:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:04:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 16:04:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:27:58
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:04:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 11:20:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 16:04:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:20:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:28:08
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 15:59:39

US3812293

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:20:44

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:28:08
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 15:59:39

US3812293

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:28:24
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 19:09:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

[If No, reason not given](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:28:24
User entered 'Confirmed COVID-19 (COVID)'	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 19:09:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:28:24
User entered empty.	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 19:09:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 19:09:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:28:24
User entered empty.	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 19:09:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:28:24
User entered empty.	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 19:09:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 19:09:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:28:24
User entered empty.	Breanna Galibert (b) (4) (b) (4)	28 Sep 2020 19:09:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:28:24
User entered empty.	System	28 Sep 2020 19:09:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 11:20:44

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 19:09:47

US3812293

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:28:42
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:02:17

US3812293

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:28:42
User entered '28 Sep 2020'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:02:17

US3812293

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:28:42
User entered '14:25'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:02:17

US3812293

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '28 Sep 2020 14:25'	System	30 Sep 2020 16:02:17

US3812293

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 11:20:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:28:56
User entered '28 Sep 2020'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:02:42

US3812293

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:20:44

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Breanna Galibert (b) (4)	30 Sep 2020 16:02:42

US3812293

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:20:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:28:56
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:02:42

US3812293

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:20:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:28:56
User entered '14:30'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:02:42

US3812293

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '28 Sep 2020 14:30'	System	30 Sep 2020 16:02:42

US3812293

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:20:44

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Breanna Galibert (b) (4)	30 Sep 2020 16:02:42

US3812293

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:20:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:28:56
User entered 'No (N)'	Breanna Galibert (b) (4)	30 Sep 2020 16:02:42
	(b) (4)	

US3812293

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:20:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:28:56
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:02:42

US3812293

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 16:02:42

US3812293

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:29:06
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	05 Oct 2020 19:19:30

US3812293

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 19:19:30

US3812293

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:51:15
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	05 Oct 2020 19:19:40

US3812293

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:51:15
User entered '5 Oct 2020'	Karen Knapp (b) (4) (b) (4)	05 Oct 2020 19:19:40

US3812293

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:51:15
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4) (b) (4)	05 Oct 2020 19:19:40

US3812293

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:51:15
User entered empty.	Karen Knapp (b) (4) (b) (4)	05 Oct 2020 19:19:40

US3812293

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:51:25
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	05 Oct 2020 19:19:46

US3812293

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Oct 2020 19:19:46

US3812293

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:52:56
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	12 Oct 2020 17:10:32

US3812293

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:52:56
User entered '12 Oct 2020'	Karen Knapp (b) (4) (b) (4)	12 Oct 2020 17:10:32

US3812293

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:52:56
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4) (b) (4)	12 Oct 2020 17:10:32

US3812293

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:52:56
User entered empty.	Karen Knapp (b) (4) (b) (4)	12 Oct 2020 17:10:32

US3812293

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:53:07
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	12 Oct 2020 17:10:36

US3812293

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 17:10:36

US3812293

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:53:30
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	19 Oct 2020 15:03:23

US3812293

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:53:30
User entered '19 Oct 2020'	Karen Knapp (b) (4) (b) (4)	19 Oct 2020 15:03:23

US3812293

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:53:30
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4) (b) (4)	19 Oct 2020 15:03:23

US3812293

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:53:30
User entered empty.	Karen Knapp (b) (4) (b) (4)	19 Oct 2020 15:03:23

US3812293

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:53:41
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	19 Oct 2020 15:03:28

US3812293

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 15:03:28

US3812293

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:54:03
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 15:44:58

US3812293

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:54:03
User entered '23 Oct 2020'	Breanna Galibert (b) (4)	26 Oct 2020 15:44:58
	(b) (4)	

US3812293

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:54:03
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 15:44:58

US3812293

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 11:20:44

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	26 Oct 2020 15:44:58

US3812293

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:54:47
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 15:45:15

US3812293

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:54:47
User entered '23 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 15:45:15

US3812293

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:54:47
User entered '14:25'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 15:45:15

US3812293

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '23 Oct 2020 14:25'	System	26 Oct 2020 15:45:15

US3812293

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

Temperature (xxx.x)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:54:47
User entered '97.1' F	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 15:45:15

US3812293

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Route of measurement](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:54:47
User entered 'Oral (Oral)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 15:45:15

US3812293

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[If Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:54:47
User entered empty.	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 15:45:15

US3812293

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:54:47
User entered '66'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 15:45:15

US3812293

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	26 Oct 2020 15:45:15

US3812293

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:54:47
User entered '17'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 15:45:15

US3812293

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	26 Oct 2020 15:45:15

US3812293

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:54:47
User entered '110'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 15:45:15

US3812293

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Oct 2020 15:45:15

US3812293

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:54:47
User entered '70'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 15:45:15

US3812293

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 11:20:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	26 Oct 2020 15:45:15

US3812293

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:20:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:55:09
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 15:45:21

US3812293

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 11:20:44

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:55:09
User entered empty.	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 15:45:21

US3812293

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:55:28
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 15:45:37

US3812293

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:55:28
User entered '23 Oct 2020'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 15:45:37

US3812293

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:55:28
User entered '14:35'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 15:45:37

US3812293

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered '23 Oct 2020 14:35'	System	26 Oct 2020 15:45:37

US3812293

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 18:55:38
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	26 Oct 2020 15:44:51

US3812293

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Oct 2020 15:44:51

US3812293

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 19:09:34
User entered 'Day 64'	System	28 Aug 2020 19:09:34

US3812293

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 (c0ec84f1f0797aec)', Time: '2020-11-01T09:44:23', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '21954c50-efdc-4396-8232-af47287e0156'	System	01 Nov 2020 15:45:15
User entered 'No (N)'	System	01 Nov 2020 15:45:15

US3812293

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Have you been exposed to someone with 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 (c0ec84f1f0797aec)', Time: '2020-11-01T09:44:29', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '21954c50-efdc-4396-8232-af47287e0156'	System	01 Nov 2020 15:45:15
User entered 'No (N)'	System	01 Nov 2020 15:45:15

US3812293

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-11-01T09:44:36', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '21954c50-efdc-4396-8232-af47287e0156'	System	01 Nov 2020 15:45:15
User entered '01 Nov 2020 09:44:36'	System	01 Nov 2020 15:45:15

US3812293

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 19:09:34
User entered '28 Oct 2020 00:01'	System	28 Aug 2020 19:09:34

US3812293

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 19:09:34
User entered '01 Nov 2020 23:59'	System	28 Aug 2020 19:09:34

US3812293

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 19:09:34
User entered 'Day 71'	System	28 Aug 2020 19:09:34

US3812293

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

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 (c0ec84f1f0797aec)', Time: '2020-11-04T02:38:40', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '34ae0dae-50e3-4d40-9af4-3819b56c3860'	System	04 Nov 2020 08:39:36
User entered 'No (N)'	System	04 Nov 2020 08:39:36

US3812293

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

Have you been exposed to someone with 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 (c0ec84f1f0797aec)', Time: '2020-11-04T02:38:49', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '34ae0dae-50e3-4d40-9af4-3819b56c3860'	System	04 Nov 2020 08:39:36
User entered 'No (N)'	System	04 Nov 2020 08:39:36

US3812293

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-11-04T02:38:59', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '34ae0dae-50e3-4d40-9af4-3819b56c3860'	System	04 Nov 2020 08:39:36
User entered '04 Nov 2020 02:38:59'	System	04 Nov 2020 08:39:36

US3812293

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 19:09:34
User entered '04 Nov 2020 00:01'	System	28 Aug 2020 19:09:34

US3812293

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 19:09:34
User entered '08 Nov 2020 23:59'	System	28 Aug 2020 19:09:34

US3812293

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 19:09:34
User entered 'Day 78'	System	28 Aug 2020 19:09:34

US3812293

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[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 (c0ec84f1f0797aec)', Time: '2020-11-14T09:09:01', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '4ba66075-f526-4925-8651-2d6d5d195925'	System	14 Nov 2020 15:09:57
User entered 'No (N)'	System	14 Nov 2020 15:09:57

US3812293

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

Have you been exposed to someone with 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 (c0ec84f1f0797aec)', Time: '2020-11-14T09:09:04', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '4ba66075-f526-4925-8651-2d6d5d195925'	System	14 Nov 2020 15:09:57
User entered 'No (N)'	System	14 Nov 2020 15:09:57

US3812293

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-11-14T09:09:10', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: '4ba66075-f526-4925-8651-2d6d5d195925'	System	14 Nov 2020 15:09:57
User entered '14 Nov 2020 09:09:10'	System	14 Nov 2020 15:09:57

US3812293

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 19:09:34
User entered '11 Nov 2020 00:01'	System	28 Aug 2020 19:09:34

US3812293

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	28 Aug 2020 19:09:34
User entered '15 Nov 2020 23:59'	System	28 Aug 2020 19:09:34

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '25 Oct 2020 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '29 Oct 2020 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '01 Nov 2020 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '05 Nov 2020 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '08 Nov 2020 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '12 Nov 2020 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '15 Nov 2020 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '19 Nov 2020 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[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 (c0ec84f1f0797aec)', Time: '2020-11-22T08:03:04', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'c17483e5-749b-4279-9840-738da54cbc4d'	System	22 Nov 2020 14:04:30
User entered 'No (N)'	System	22 Nov 2020 14:04:30

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

Have you been exposed to someone with 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 (c0ec84f1f0797aec)', Time: '2020-11-22T08:03:15', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'c17483e5-749b-4279-9840-738da54cbc4d'	System	22 Nov 2020 14:04:30
User entered 'Yes (Y)'	System	22 Nov 2020 14:04:30

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Please 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 (c0ec84f1f0797aec)', Time: '2020-11-22T08:03:24', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'c17483e5-749b-4279-9840-738da54cbc4d'	System	22 Nov 2020 14:04:30
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Nov 2020 14:04:30

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c0ec84f1f0797aec)', Time: '2020-11-22T08:03:31', User OID: 'PatientReportedOutcome (US3812293)', ODM File OID: 'c17483e5-749b-4279-9840-738da54cbc4d'	System	22 Nov 2020 14:04:30
User entered '22 Nov 2020 08:03:31'	System	22 Nov 2020 14:04:30

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '16 Oct 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '20 Oct 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '23 Oct 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '27 Oct 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '30 Oct 2022 00:01'	System	19 Nov 2020 20:05:35

US3812293

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 11:20:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 20:05:35
Amendment Manager: User entered '03 Nov 2022 23:59'	System	19 Nov 2020 20:05:35

US3812293

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	23 Nov 2020 15:38:13

US3812293

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Karen Knapp (b) (4) (b) (4)	23 Nov 2020 15:38:13

US3812293

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4) (b) (4)	23 Nov 2020 15:38:13

US3812293

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 11:20:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Karen Knapp (b) (4) (b) (4)	23 Nov 2020 15:38:13

US3812293

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Karen Knapp (b) (4) (b) (4)	23 Nov 2020 15:38:17

US3812293

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 11:20:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 15:38:17

US3812293

Folder: Covid-19 Assessment 28 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:20:44

[Date of Contact](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020'	Lyly Dang (b) (4)	04 Sep 2020 22:31:02

US3812293

Folder: Covid-19 Assessment 28 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:20:44

[Time of Contact](#)

Audit	User	Time (GMT)
User entered '12:57'	Lyly Dang (b) (4)	04 Sep 2020 22:31:02

US3812293

Folder: Covid-19 Assessment 28 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:20:44

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:57'	System	04 Sep 2020 22:31:02

US3812293

Folder: Covid-19 Assessment 28 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:20:44

[Type of Contact](#)

Audit	User	Time (GMT)
User entered 'Clinic Visit - Scheduled (Clinic Visit - Scheduled)'	Lyly Dang (b) (4)	04 Sep 2020 22:31:02

US3812293

Folder: Covid-19 Assessment 28 Aug 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 11:20:44

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Lyly Dang (b) (4) [REDACTED] [REDACTED]	04 Sep 2020 22:31:02

US3812293

Folder: Covid-19 Assessment 28 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 11:20:44

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Karen Knapp (b) (4) (b) (4)	18 Oct 2020 13:13:58

US3812293

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 11:20:44

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)' reason for change: New Information	Breanna Galibert (b) (4)	30 Sep 2020 16:12:45
User entered 'No (N)'	Karen Knapp (b) (4)	11 Sep 2020 18:33:35

US3812293

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Skin structures and soft tissue infections, PT: Subcutaneous abscess, LLT: Axillary abscess - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 00:30:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 00:30:17
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:15:45
Data point term sent to Coder	System	30 Sep 2020 16:16:08
User entered 'LEFT AXILLARY ABSCESS'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:15:50

US3812293

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:15:45
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:15:50

US3812293

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:15:45
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:15:50

US3812293

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:15:45
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:15:50

US3812293

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:15:45
User entered '06 Sep 2020'	Breanna Galibert (b) (4)	30 Sep 2020 16:15:50
	(b) (4)	

US3812293

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:15:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:15:50

US3812293

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 16:15:50

US3812293

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:15:45
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:15:50

US3812293

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:15:45
User entered '17 Sep 2020'	Breanna Galibert (b) (4)	30 Sep 2020 16:15:50
	(b) (4)	

US3812293

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:15:45
User entered empty.	Breanna Galibert (b) (4)	30 Sep 2020 16:15:50
	(b) (4)	

US3812293

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 16:15:50

US3812293

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:15:45
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Breanna Galibert (b) (4)	30 Sep 2020 16:15:50
	(b) (4)	

US3812293

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:15:45
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:15:50

US3812293

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:15:45
User entered '0'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:15:50

US3812293

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:15:45
User entered '0'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:15:50

US3812293

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:15:45
User entered '0'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:15:50

US3812293

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:15:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:15:50

US3812293

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:15:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:15:50

US3812293

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:15:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:15:50

US3812293

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:15:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:15:50

US3812293

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:15:45
User entered '0'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:15:50

US3812293

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:15:45
User entered '0'	Breanna Galibert (b) (4)	30 Sep 2020 16:15:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:15:45
User entered '0'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:15:50

US3812293

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:15:45
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:15:50

US3812293

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:15:45
User entered 'Not Related (NOT RELATED)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:15:50

US3812293

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:15:45
User entered 'Not Applicable (NOT APPLICABLE)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:15:50

US3812293

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:15:45
User entered '0'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:15:50

US3812293

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:15:45
User entered '1'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:15:50

US3812293

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Per previous query response "Updated"; however, please provide location of update such as log line number. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 09:16:46
Query 'Per CDM: Per previous query response "Updated"; however, please provide location of update such as log line number. Thank you.' answered with 'PROCEDURE WAS ENTERED INTO CONCOMITANT PROCEDURE LOG LINE ONE' (Site from DM).	Breanna Galibert (b) (4)	20 Nov 2020 20:42:29
User opened query 'Per CDM: Per previous query response "Updated"; however, please provide location of update such as log line number. Thank you.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 08:43:58
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 08:39:44
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'updated EDC per source' (Site from DM).	Anya Penly (b) (4)	12 Nov 2020 22:06:11
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 04:18:02
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:15:45
User entered '1'	Breanna Galibert (b) (4)	30 Sep 2020 16:15:50

US3812293

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:15:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:15:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:15:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:15:50

US3812293

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:15:45
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:15:50

US3812293

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	30 Sep 2020 16:15:50

US3812293

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 11:20:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	30 Sep 2020 16:15:50

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 11:20:44

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:33:30
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:31:39

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 23:33:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 23:33:43
Data point term sent to Coder	System	05 Sep 2020 23:32:56
User entered 'LISINOPRIL'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:32:06

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:32:06

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered 'HYPERTENSION'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:32:06

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered '5'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:32:06

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered 'mg (mg)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:32:06

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered empty.	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:32:06

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered 'once daily (QD)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:32:06

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered empty.	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:32:06

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered 'Oral (ORAL)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:32:06

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered empty.	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:32:06

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered 'UN UNK 2018'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:32:06

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered '0'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:32:06

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:32:06

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered empty.	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:32:06

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:32:06

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 23:32:06

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 23:32:06

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Sep 2020 23:32:06

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 23:33:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 23:33:43
Data point term sent to Coder	System	05 Sep 2020 23:32:56
User entered 'MULTI VITAMIN'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:32:42

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:32:42

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered 'GENERAL HEALTH'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:32:42

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered '1'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:32:42

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered 'tablet (TABLET)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:32:42

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered empty.	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:32:42

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered 'once daily (QD)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:32:42

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered empty.	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:32:42

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered 'Oral (ORAL)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:32:42

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered empty.	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:32:42

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered 'UN UNK 2000'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:32:42

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered '0'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:32:42

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:32:42

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered empty.	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:32:42

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	05 Sep 2020 23:32:42

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 23:32:42

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 23:32:42

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Sep 2020 23:32:42

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 06:48:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Oct 2020 06:48:35
Data point term sent to Coder	System	30 Sep 2020 16:11:59
User entered 'TRAMADOL'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:11:21

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:11:21

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered 'PAIN AT I&D SITE'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:11:21

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered '50'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:11:21

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:11:21

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:11:21

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered 'as needed (PRN)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:11:21

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:11:21

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:11:21

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:11:21

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered '07 Sep 2020'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:11:21

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered '0'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:11:21

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:11:21

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered '07 Sep 2020'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:11:21

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:11:21

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 16:11:21

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 16:11:21

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 16:11:21

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALEXIN, PRODUCTSYNONYM: CEPHALEXIN [CEFALEXIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 17:59:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 17:59:53
Data point term sent to Coder	System	30 Sep 2020 16:13:01
User entered 'CEPHALEXIN'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:12:35

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:12:35

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please update the indication to reflect the location/type of ABSCESS. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 07:47:31
User opened query 'Per DM CLR: Please update the indication to reflect the location/type of ABSCESS. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 07:38:16
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered 'ABSCESS'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:12:35

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered '500'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:12:35

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered 'mg (mg)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:12:35

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:12:35

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered 'as needed (PRN)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:12:35

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:12:35

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:12:35

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered empty.	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:12:35

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered '07 Sep 2020'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:12:35

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered '0'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:12:35

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:12:35

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered '17 Sep 2020'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:12:35

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:34:56
User entered 'No (N)'	Breanna Galibert (b) (4) (b) (4)	30 Sep 2020 16:12:35

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 16:12:35

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 16:12:35

US3812293

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 11:20:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Sep 2020 16:12:35

US3812293

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 11:20:44

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Anya Penly (b) (4)	12 Nov 2020 21:46:05
	(b) (4)	
User entered 'Yes (Y)' reason for change: New Information	Anya Penly (b) (4)	12 Nov 2020 21:46:05
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:36:10
	(b) (4), (b) (6)	
Query 'Conmeds are listed in source. Please update accordingly, ' canceled (Site from CRA).	(b) (4), (b) (6)	05 Oct 2020 20:34:31
	(b) (4), (b) (6)	
User opened query 'Conmeds are listed in source. Please update accordingly, ' (Site from CRA).	(b) (4), (b) (6)	05 Oct 2020 20:17:08
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	05 Oct 2020 20:16:17
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 20:16:15
	(b) (4)	
User entered 'No (N)'	Karen Knapp (b) (4)	13 Sep 2020 11:53:19
	(b) (4)	

US3812293

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:20:44

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '7 Sep 2020'	Anya Penly (b) (4) (b) (4)	12 Nov 2020 22:05:33

US3812293

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:20:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User entered 'Incision and drainage'	Anya Penly (b) (4) (b) (4)	12 Nov 2020 22:05:33

US3812293

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:20:44

[Indication](#)

Audit	User	Time (GMT)
User entered 'Adverse Event (AE)'	Anya Penly (b) (4) (b) (4)	12 Nov 2020 22:05:33

US3812293

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 11:20:44

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Anya Penly (b) (4) (b) (4)	12 Nov 2020 22:05:33

US3812293

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:20:44

Date of dosing discontinuation (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CDM: Per pages 38-39 of CCGs version 2.0, "Date of dosing discontinuation" should be the same as date of last exposure. If the subject discontinues the study as well (i.e. not being followed) please fill in the "End of Study/Study Discontinuation" form and date it with the date of last contact. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 14:53:30
Query 'Per CDM: Per pages 38-39 of CCGs version 2.0, "Date of dosing discontinuation" should be the same as date of last exposure. If the subject discontinues the study as well (i.e. not being followed) please fill in the "End of Study/Study Discontinuation" form and date it with the date of last contact. Thank you.' answered with 'EDC updated. Thank you!' (Site from DM).	Lyly Dang (b) (4)	26 Oct 2020 18:31:07
User entered '28 Aug 2020' reason for change: Data Entry Error	Lyly Dang (b) (4)	26 Oct 2020 18:30:40
User opened query 'Per CDM: Per pages 38-39 of CCGs version 2.0, "Date of dosing discontinuation" should be the same as date of last exposure. If the subject discontinues the study as well (i.e. not being followed) please fill in the "End of Study/Study Discontinuation" form and date it with the date of last contact. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 12:41:15
User entered '28 Sep 2020' reason for change: Data Entry Error	Breanna Galibert (b) (4)	05 Oct 2020 13:12:40
User entered '2 Sep 2020'	Lyly Dang (b) (4)	03 Oct 2020 23:17:22

US3812293

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:20:44

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Per CCGs pages 38-39 of CCGs version 2.0 (enter due to SARS-COV-2 if participant is diagnosed). Please confirm if patient was diagnosed. Also complete the Covid-19 Assessment and AE pages. Thank you. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 14:53:19
Query 'Per CDM: Per CCGs pages 38-39 of CCGs version 2.0 (enter due to SARS-COV-2 if participant is diagnosed). Please confirm if patient was diagnosed. Also complete the Covid-19 Assessment and AE pages. Thank you. ' answered with 'Subject was positive for SARS-COV2 at baseline visit on 28 Aug 2020; therefore, no AE page was written or COVID-19 Assessment was performed. Thank you!' (Site from DM).	Lyly Dang (b) (4)	26 Oct 2020 18:31:51
User opened query 'Per CDM: Per CCGs pages 38-39 of CCGs version 2.0 (enter due to SARS-COV-2 if participant is diagnosed). Please confirm if patient was diagnosed. Also complete the Covid-19 Assessment and AE pages. Thank you. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 12:41:40
User entered 'Due to SARS-COV-2 (COVID)'	Lyly Dang (b) (4)	03 Oct 2020 23:17:22

US3812293

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 11:20:44

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

Audit	User	Time (GMT)
User entered empty.	Lyly Dang (b) (4)	03 Oct 2020 23:17:22