

US3432260 (Prod: Brigham and Womens Hospital)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:23:31

All time stamps listed in this document are displayed in GMT

US3432260

Form: Participant Creation

Generated On: 26 Nov 2020 09:23:31

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:23:31

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	24 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 09:23:31

Date of Birth (MMM yyyy)	(b) (6) 1975
Age	45
Age Units	YEARS
Age (Derived)	45
Sex	Female ☒ Male ☐
Ethnicity	Hispanic or Latino ☒ Not Hispanic or Latino ☐ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	False
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	True
If race is Other, specify	LATIN
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:31

Date of Informed Consent (<i>dd MMM yyyy</i>)	24 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 09:23:31

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:23:31

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:31

Condition	SPONDYLOARTHRITIS
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 (2)

Generated On: 26 Nov 2020 09:23:31

Condition	CERVICAL COMPRESSION
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 (3)

Generated On: 26 Nov 2020 09:23:31

Condition	GERD
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:31

Condition	MIGRAINES
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Start Year (derived)	2019
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:31

Condition	CHRONIC SINUSITIS
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 (6)

Generated On: 26 Nov 2020 09:23:31

Condition	SEASONAL ALLERGIES
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 (7)

Generated On: 26 Nov 2020 09:23:31

Condition	HYSTERECTOMY (FIBROIDS)
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	24 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	11:50 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 11:50
Height (<i>xxx.x</i>)	173 cm
Weight (<i>xxx.x</i>)	73.4 kg
BMI (<i>xxx.x</i>)	24.52471 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral ☐
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 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 09:23:31

Date of assessment (<i>dd MMM yyyy</i>)	24 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 2017
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 09:23:31

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)	Yes ☒	No ☐
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)	Yes ☐	No ☒
Retail or Restaurant Operations , particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)	Yes ☐	No ☒
Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)	Yes ☐	No ☒
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)	Yes ☐	No ☒
Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)	Yes ☐	No ☒
Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)	Yes ☐	No ☒
Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)	Yes ☐	No ☒
Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)	Yes ☐	No ☒
Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)	Yes ☐	No ☒
Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)	Yes ☐	No ☒
Other	Yes ☐	No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified	False
Resides in Nursing Home or Assisted Living Facility	False
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

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

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:23:31

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	24 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 09:23:31

What was the date of randomization? (dd MMM yyyy) 24 AUG 2020

What was the participant's randomization number? 107801

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 09:23:31

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 09:23:31

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)	24 AUG 2020
Time of assessment (00:00-23:59)	11:50 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 11:50
Temperature (xxx.x)	36.5 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 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 09:23:31

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)	24 AUG 2020
Time of assessment (00:00-23:59)	13:18 (24 HR)
Vital Signs Date and Time (derived)	24 AUG 2020 13:18
Temperature (xxx.x)	37.2 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:31

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 09:23:31

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) 24 AUG 2020

What was the treatment time? (00:00-23:59) 12:48 (24 HR)

Treatment Date and Time (derived) 24 AUG 2020 12:48

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 09:23:31

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

24 AUG 2020

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

12:17 (24 HR)

Collection date and time (derived)

24 AUG 2020 12:17

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:23:31

Collection date (<i>dd MMM yyyy</i>)			24 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	12:25	24 AUG 2020 12:25
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:23:31

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 09:23:31

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

98.9 °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 24 AUG 2020 13:20

PC Open Date & Time 24 AUG 2020 13:08

PC Close Date & Time 24 AUG 2020 15:38

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

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

98.7 °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

24 AUG 2020 20:18

PC Open Date & Time

24 AUG 2020 16:33

PC Close Date & Time

25 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:31

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 16:53

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

26 AUG 2020 12:14

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes ☒
	No ☐
Please record your TEMPERATURE in °F	98.7 °F
Was any MEDICATION TAKEN today for pain or fever ?	Yes ☒
	No ☐

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

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

PC Time Stamp	27 AUG 2020 16:18
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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 13:52

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:31

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

29 AUG 2020 14:12

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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 14:18

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

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

24 AUG 2020 13:21

PC Open Date & Time

24 AUG 2020 13:08

PC Close Date & Time

24 AUG 2020 15:38

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

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 ☐

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

1

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

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

Yes ☐

No ☒

Please record - **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

24 AUG 2020 20:20

PC Open Date & Time

24 AUG 2020 16:33

PC Close Date & Time

25 AUG 2020 11:59

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:31

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

25 AUG 2020 16:53

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:31

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

26 AUG 2020 12:15

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:31

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

27 AUG 2020 16:19

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:31

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

28 AUG 2020 13:52

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:31

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

29 AUG 2020 14:12

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:31

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

30 AUG 2020 14:18

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 13:21
PC Open Date & Time	24 AUG 2020 13:08
PC Close Date & Time	24 AUG 2020 15:38

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

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

No ☒

Yes ☐

PC Time stamp	24 AUG 2020 20:19
PC Open Date & Time	24 AUG 2020 16:33
PC Close Date & Time	25 AUG 2020 11:59

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:31

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 ☒

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:31

Yes ☐	
PC Time stamp	25 AUG 2020 16:53
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:31

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 ☒

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:31

Yes ☐	
PC Time stamp	26 AUG 2020 12:15
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:31

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 ☒

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:31

Yes ☐	
PC Time stamp	27 AUG 2020 16:19
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:31

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 ☒

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:31

Yes ☐	
PC Time stamp	28 AUG 2020 13:52
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:31

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 ☒

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:31

Yes ☐	
PC Time stamp	29 AUG 2020 14:12
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:31

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 ☒

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:31

Yes ☐	
PC Time stamp	30 AUG 2020 14:19
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3432260

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

31 AUG 2020 16:23

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3432260

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp 01 SEP 2020 18:09

PC Open Date & Time 01 SEP 2020 12:00

PC Close Date & Time 02 SEP 2020 11:59

US3432260

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

02 SEP 2020 12:00

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3432260

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your

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 ☐

PC Time Stamp 03 SEP 2020 12:06

PC Open Date & Time 03 SEP 2020 12:00

PC Close Date & Time 04 SEP 2020 11:59

US3432260

Folder: Diary Dose 1 (1)

Form: Headache_Day(12)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your

None ☐

HEADACHE

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 ☐

PC Time Stamp

04 SEP 2020 12:01

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3432260

Folder: Diary Dose 1 (1)

Form: Headache_Day(13)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your

None ☒

HEADACHE

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 ☐

PC Time Stamp 05 SEP 2020 15:28

PC Open Date & Time 05 SEP 2020 12:00

PC Close Date & Time 06 SEP 2020 11:59

US3432260

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 8

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

31 AUG 2020 16:23

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3432260

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:23:31

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

01 SEP 2020 18:09

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3432260

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 09:23:31

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

02 SEP 2020 12:00

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3432260

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 09:23:31

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

03 SEP 2020 12:06

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3432260

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 31 AUG 2020 16:23

PC Open Date & Time 31 AUG 2020 12:00

PC Close Date & Time 01 SEP 2020 11:59

US3432260

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 8

Select one response below to indicate the level of your

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 ☐

PC Time stamp

31 AUG 2020 16:23

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3432260

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 9

Select one response below to indicate the level of your

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 ☐

PC Time stamp 01 SEP 2020 18:10

PC Open Date & Time 01 SEP 2020 12:00

PC Close Date & Time 02 SEP 2020 11:59

US3432260

Folder: Diary Dose 1 (1)

Form: Nausea_Day(10)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 10

Select one response below to indicate the level of your

None ☒

NAUSEA/VOMITING

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 ☐

PC Time stamp

02 SEP 2020 12:23

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3432260

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	31 AUG 2020 16:23
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3432260

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	01 SEP 2020 18:10
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3432260

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	02 SEP 2020 12:23
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3432260

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	03 SEP 2020 12:06
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3432260

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 13

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

No ☐

Yes ☒

PC Time stamp

05 SEP 2020 15:28

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3432260

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:31

Was Contact Attempted?

Yes ☒

No ☐

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

01 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432260

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432260

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432260

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432260

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:31

Was Contact Attempted?

Yes ☒

No ☐

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

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432260

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432260

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:31

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	21 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3432260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:31

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	21 SEP 2020
Time of assessment (00:00-23:59)	11:16 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 11:16
Temperature (xxx.x)	99.0 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3432260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:31

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	21 SEP 2020
Time of assessment (00:00-23:59)	12:51 (24 HR)
Vital Signs Date and Time (derived)	21 SEP 2020 12:51
Temperature (xxx.x)	98.4 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3432260

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

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

US3432260

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:31

Was study treatment given?	Yes ☒
	No ☐
If No, reason not given	Participant declined due to Adverse Event ☐
	Physician withheld dose due to Adverse Event ☐
	Death ☐
	Lost To Follow-Up ☐
	Physician Decision ☐
	Pregnancy ☐
	Protocol Deviation ☐
	Study Terminated by Sponsor ☐
	Withdrawal of Consent by Participant ☐
	Confirmed COVID-19 ☐
	Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	21 SEP 2020
What was the treatment time? (00:00-23:59)	12:17 (24 HR)
Treatment Date and Time (derived)	21 SEP 2020 12:17
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

US3432260

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:31

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	21 SEP 2020
Collection time (<i>00:00-23:59</i>)	11:46 (24 HR)
Collection date and time (derived)	21 SEP 2020 11:46

US3432260

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:23:31

Collection date (dd MMM yyyy)			21 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:00	21 SEP 2020 12:00
Nasopharyngeal Swab 2	No		

US3432260

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 12:55

PC Open Date & Time

21 SEP 2020 12:37

PC Close Date & Time

21 SEP 2020 15:07

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐
No ☒

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

PC Time Stamp	21 SEP 2020 17:21
PC Open Date & Time	21 SEP 2020 16:02
PC Close Date & Time	22 SEP 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:31

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

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

22 SEP 2020 19:27

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:31

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

98.6 °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

24 SEP 2020 07:16

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes ☒
	No ☐
Please record your TEMPERATURE in °F	98.9 °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):

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

PC Time Stamp	25 SEP 2020 06:21
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 12:07

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:31

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

99.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 20:14

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:31

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

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 07:22

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

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

21 SEP 2020 12:55

PC Open Date & Time

21 SEP 2020 12:37

PC Close Date & Time

21 SEP 2020 15:07

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 17:22

PC Open Date & Time

21 SEP 2020 16:02

PC Close Date & Time

22 SEP 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 19:27

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 07:16

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:31

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

25 SEP 2020 06:21

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 SEP 2020 12:08

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:31

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

26 SEP 2020 20:14

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:31

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

28 SEP 2020 07:23

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 12:56
PC Open Date & Time	21 SEP 2020 12:37
PC Close Date & Time	21 SEP 2020 15:07

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

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

No ☒

Yes ☐

PC Time stamp	21 SEP 2020 17:22
PC Open Date & Time	21 SEP 2020 16:02
PC Close Date & Time	22 SEP 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:31

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 ☒

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:31

Yes ☐	
PC Time stamp	22 SEP 2020 19:27
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:31

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 ☒

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:31

Yes ☐	
PC Time stamp	24 SEP 2020 07:17
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:31

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 ☒

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:31

Yes ☐	
PC Time stamp	25 SEP 2020 06:22
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:31

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 ☒

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:31

Yes ☐	
PC Time stamp	25 SEP 2020 12:14
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:31

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 ☒

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:31

Yes ☐	
PC Time stamp	26 SEP 2020 20:14
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:31

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 ☒

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:31

Yes ☐	
PC Time stamp	28 SEP 2020 07:23
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp	29 SEP 2020 09:48

PC Open Date & Time	28 SEP 2020 12:00

PC Close Date & Time	29 SEP 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 9

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

None ☐

ACHES IN SEVERAL JOINTS

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 10

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 30 SEP 2020 13:36

PC Open Date & Time 30 SEP 2020 12:00

PC Close Date & Time 01 OCT 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 11

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 01 OCT 2020 16:38

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 12

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 02 OCT 2020 20:00

PC Open Date & Time 02 OCT 2020 12:00

PC Close Date & Time 03 OCT 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 13

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 04 OCT 2020 07:57

PC Open Date & Time 03 OCT 2020 12:00

PC Close Date & Time 04 OCT 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 14

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 05 OCT 2020 06:30

PC Open Date & Time 04 OCT 2020 12:00

PC Close Date & Time 05 OCT 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 15

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 05 OCT 2020 12:00

PC Open Date & Time 05 OCT 2020 12:00

PC Close Date & Time 06 OCT 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 16

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

None ☐

ACHES IN SEVERAL JOINTS

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 17

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 08 OCT 2020 09:35

PC Open Date & Time 07 OCT 2020 12:00

PC Close Date & Time 08 OCT 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 18

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 09 OCT 2020 11:22

PC Open Date & Time 08 OCT 2020 12:00

PC Close Date & Time 09 OCT 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of **CHILLS** you are experiencing

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

PC Open Date & Time	28 SEP 2020 12:00

PC Close Date & Time	29 SEP 2020 11:59

PC Time stamp	29 SEP 2020 09:48

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	29 SEP 2020 09:48
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 10

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

No ☐

Yes ☒

PC Time stamp

30 SEP 2020 13:36

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT	DAY 11
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	01 OCT 2020 16:38
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	02 OCT 2020 20:00
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT	DAY 13
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	04 OCT 2020 07:57
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT	DAY 14
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	05 OCT 2020 06:30
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT	DAY 15
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	05 OCT 2020 12:00
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 16

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

06 OCT 2020 12:00

PC Close Date & Time

07 OCT 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 17

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

No ☒

Yes ☐

PC Time stamp

08 OCT 2020 09:36

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT	DAY 18
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	09 OCT 2020 11:22
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3432260

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:31

Was Contact Attempted?

Yes ☒

No ☐

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

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432260

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432260

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:31

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

US3432260

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432260

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:31

Was Contact Attempted?

Yes ☒

No ☐

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

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432260

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432260

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:31

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	24 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3432260

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	24 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	10:33 (24 HR)
Vital Signs Date and Time (derived)	24 OCT 2020 10:33
Temperature (<i>xxx.x</i>)	97.3 F
Route of measurement	Oral ☐
	Axillary ☐
	Other ☒
If Other, specify	INFRARED
Pulse (<i>xxx</i>)	66 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432260

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:31

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.

US3432260

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:31

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 OCT 2020

Collection time (00:00-23:59)

11:17 (24 HR)

Collection date and time (derived)

24 OCT 2020 11:17

US3432260

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

28 OCT 2020 11:59:31

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3432260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐
Have 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):	
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 ☒
Please contact your study clinic immediately. Click below to confirm that you have read this 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	04 NOV 2020 14:56:45
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

US3432260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 contact your study clinic immediately. Click below to confirm that you have read this 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	10 NOV 2020 18:00:09
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

25 OCT 2020 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

01 NOV 2020 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

08 NOV 2020 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

15 NOV 2020 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐
Have 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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	True
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
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 ☐
Date and time of submission	21 NOV 2020 06:05:11
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

29 NOV 2020 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

06 DEC 2020 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

13 DEC 2020 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

20 DEC 2020 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

27 DEC 2020 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

03 JAN 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

10 JAN 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

17 JAN 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

24 JAN 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

31 JAN 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

07 FEB 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

14 FEB 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

21 FEB 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

28 FEB 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

07 MAR 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

14 MAR 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

21 MAR 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

28 MAR 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

04 APR 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

11 APR 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

18 APR 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

25 APR 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

02 MAY 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

16 MAY 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

15 AUG 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

29 AUG 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

17 OCT 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

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31 OCT 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

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07 NOV 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

14 NOV 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

05 DEC 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

19 DEC 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

26 DEC 2021 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT	DAY 509
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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°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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

30 JAN 2022 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

20 MAR 2022 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

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27 MAR 2022 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

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03 APR 2022 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

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17 APR 2022 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

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24 APR 2022 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

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01 MAY 2022 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

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08 MAY 2022 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

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22 MAY 2022 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

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29 MAY 2022 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

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05 JUN 2022 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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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08 JUN 2022 00:01

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12 JUN 2022 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

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19 JUN 2022 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

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26 JUN 2022 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

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

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US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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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21 AUG 2022 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

Please contact your study clinic immediately. Click below to confirm that you have read this 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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24 AUG 2022 00:01

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28 AUG 2022 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

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04 SEP 2022 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

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

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11 SEP 2022 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

09 OCT 2022 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

16 OCT 2022 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

23 OCT 2022 23:59

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

[Patient Cloud Close Date & Time](#)

30 OCT 2022 23:59

US3432260

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:31

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

US3432260

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:31

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:23:31

Date of Contact	21 NOV 2020
Time of Contact	10:30
Date and Time of Contact (derived)	21 NOV 2020 10:30
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 ☐

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:31

Symptom Day

Day 1	☒
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	14 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	377 of 2453	

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:31

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:31

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:31

Symptom Day

Day 1	☐
Day 2	☒
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	15 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	381 of 2453	

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:31

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:31

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:31

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☒
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	16 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None ☒	
	Mild ☐	
	Moderate ☐	
	Severe ☐	
	Not Done ☐	
Cough	None ☐	
	Mild ☒	
	Moderate ☐	
	Severe ☐	
	Not Done ☐	
Shortness of Breath	None ☒	
	Mild ☐	
	Moderate ☐	
	Severe ☐	
	Not Done ☐	
Difficulty Breathing	None ☒	
	Mild ☐	
	Moderate ☐	
	Severe ☐	
	Not Done ☐	
Fatigue	None ☒	
v6.020 DTW (1102)	385 of 2453	

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:31

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:31

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:31

[Symptom Day](#)

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☒
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	17 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	389 of 2453	

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Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:31

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐

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Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:31

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:31

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☒
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	18 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	393 of 2453	

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Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:31

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐

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Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:31

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:31

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☒
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	19 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	397 of 2453	

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Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:31

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐

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Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:31

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:31

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☒
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

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Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	20 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	401 of 2453	

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Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:31

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐

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Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:31

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

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Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:31

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☒
Day 9	☐
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

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Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	21 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	37.5 C	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	405 of 2453	

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:31

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐

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Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:31

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:31

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☒
Day 10	☐
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	22 NOV 2020	
Assessment Not Done	True	
O2 Saturation		
O2 Saturation Units		
Temperature		
Chills	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☐
v6.020 DTW (1102)	409 of 2453	

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Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:31

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☐
	Moderate	☐

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:31

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐

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Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:23:31

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☒
Day 11	☐
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

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Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:23:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	23 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	413 of 2453	

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:23:31

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☒
	Mild	☐
	Moderate	☐

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Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:23:31

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:23:31

Symptom Day

Day 1	☐
Day 2	☐
Day 3	☐
Day 4	☐
Day 5	☐
Day 6	☐
Day 7	☐
Day 8	☐
Day 9	☐
Day 10	☐
Day 11	☒
Day 12	☐
Day 13	☐
Day 14	☐
Day 15	☐
Day 16	☐
Day 17	☐
Day 18	☐
Day 19	☐
Day 20	☐
Day 21	☐
Day 22	☐
Day 23	☐
Day 24	☐
Day 25	☐
Day 26	☐
Day 27	☐
Day 28	☐
Day 29	☐
Day 30	☐
Day 31	☐
Day 32	☐
Day 33	☐

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:23:31

	Day 34	☐
	Day 35	☐
	Day 36	☐
	Day 37	☐
	Day 38	☐
	Day 39	☐
	Day 40	☐
Date	24 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	98.9 F	
Chills	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Cough	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Shortness of Breath	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Difficulty Breathing	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Fatigue	None	☒
v6.020 DTW (1102)	417 of 2453	

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Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:23:31

	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Muscle Aches (Myalgia)	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Body Aches	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Headache	None	☐
	Mild	☐
	Moderate	☒
	Severe	☐
	Not Done	☐
New Loss of Taste	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
New Loss of Smell	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Nasal Congestion	None	☐
	Mild	☒
	Moderate	☐

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:23:31

	Severe	☐
	Not Done	☐
Runny Nose (Rhinorrhea)	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐
Nausea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Vomiting	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Diarrhea	None	☒
	Mild	☐
	Moderate	☐
	Severe	☐
	Not Done	☐
Sore Throat	None	☐
	Mild	☒
	Moderate	☐
	Severe	☐
	Not Done	☐

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: COVID Diagnostic Test

Generated On: 26 Nov 2020 09:23:31

Date of Visit	
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes ☐
	No ☐
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes ☐
	No ☐
Date of Test	
Type of Test Performed	Nasopharyngeal Swab ☐
	Nasal Swab ☐
	Saliva Test ☐
	Other ☐
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes ☐
	No ☐
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes ☐
	No ☐
COVID-19 Positive (CSA Programming Field Only)	

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:23:31

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3432260

Folder: Illness Visit (1)

Form: Saliva Collection

Generated On: 26 Nov 2020 09:23:31

Visit	Was Saliva Collected?	Date of Collection
Day 3		
Day 5		
Day 7		
Day 9		
Day 14		
Day 21		
Day 28		

US3432260

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:31

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	21 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	SICKD1

US3432260

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	21 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	10:15 (24 HR)
Vital Signs Date and Time (derived)	21 NOV 2020 10:15
Height (<i>xxx.x</i>)	ND - Not Done
Weight (<i>xxx.x</i>)	ND - Not Done
Temperature (<i>xxx.x</i>)	37.5 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	79 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 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>)	79 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432260

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 NOV 2020

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

US3432260

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:23:31

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

21 NOV 2020

US3432260

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:31

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3432260

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

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

US3432260

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:31

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.

US3432260

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:23:31

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection _____

US3432260

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:23:31

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3432260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:31

AEID	
Adverse event	REACTOGENICITY SYNDROME (INTERMITTENT NAUSEA AND HEADACHE)
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)	26 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	5 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	
v6.020 DTW (1102)	
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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:31

Persistent or significant disability or incapacity	False
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	False
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)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3432260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:31

AEID	
Adverse event	SINUS INFECTION
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)	02 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)	12 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)	434 of 2453

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:31

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	False
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)	

US3432260

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

AEID	USA-US078-2020-MRNA-1273-P30 1000010
Adverse event	CERVICAL FUSION C5-C6
Was this a medically-attended AE?	Yes ☒ No ☐
Was this a Solicited Adverse Reaction?	Yes ☐ No ☒
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes ☐ No ☒
Start date (dd MMM yyyy)	04 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☒ No ☐
If not Ongoing, end date (dd MMM yyyy)	
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	True
Hospital Admission Date (dd MMM yyyy)	04 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	
v6.020 DTW (1102)	436 of 2453

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

Persistent or significant disability or incapacity	False
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	

US3432260

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

HAS PRE-EXISTING
CONDITION CERVICAL
COMPRESSION AND
SPONDYLOLISTHESIS.
UNDERWENT A PLANNED
SCHEDULED PROCEDURE
04NOV2020 FOR CERVICAL
FUSION C5-C6 WITH BONE
GRAFT AND HARDWARE
PLACEMENT. PT IS
TENTATIVELY SCHEDULED
FOR DISCHARGE TOMORROW
05NOV2020.

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

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:23:31

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

Yes ☒

No ☐

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

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:31

Name of Medication SECUKINUMAB

Prophylaxis Yes ☐
No ☒

Indication SPONDYLOARTHRITIS

Dose per administration 150

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

FIVE TIMES A WEEK

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

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:31

	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)	4 FEB 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	☐

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:31

Name of Medication	BOTOX INJECTION
Prophylaxis	Yes ☐ No ☒
Indication	CERVICAL COMPRESSION
Dose per administration	UNK
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	UNKNOWN
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☒
If frequency is Other, specify	EVERY 3 MONTHS
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☒ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:31

	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 JUN 2020	
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)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:31

Name of Medication	GABAPENTIN
Prophylaxis	Yes ☐ No ☒
Indication	PAIN RELATED TO SPONDYLOARTHRITIS
Dose per administration	100
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:31

	Intramuscular	☐
	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 2019	
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)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:31

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ☒
Indication	PAIN RELATED TO SPONDYLOARTHRITIS
Dose per administration	400
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 ☐

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:31

	Intramuscular	☐
	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 2015
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)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:31

Name of Medication	ACETAMINOPHEN
Prophylaxis	Yes ☐ No ☒
Indication	PAIN RELATED TO SPONDYLOARTHRITIS
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 ☐

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:31

	Intramuscular	☐
	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 2015
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)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:31

Name of Medication	NEXIUM
Prophylaxis	Yes ☐ No ☒
Indication	GERD
Dose per administration	20
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:31

	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 2017
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	☒

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:31

Name of Medication	MOTRIN
Prophylaxis	Yes ☐ No ☒
Indication	HEADACHE
Dose per administration	800
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 ☐

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:31

	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)	27 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy) 27 AUG 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	☐

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:31

Name of Medication	AUGMENTIN (AMOXICILLIN/CLAVULANATE)
Prophylaxis	Yes ☐ No ☒
Indication	SINUSITIS
Dose per administration	875/125
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 ☐

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:31

	Intramuscular	☐
	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)	04 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		UN SEP 2020
Was this medication taken for solicited event?	Yes ☐	
	No ☒	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 ☐	
	803 ☐	
	804 ☒	

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:31

Name of Medication	FLONASE
Prophylaxis	Yes ☐ No ☒
Indication	SEASONAL ALLERGIES
Dose per administration	2
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	SPRAYS EACH NOSTRIL
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 ☐

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:31

	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)	2 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	3 SEP 2020	
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	☒

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:31

Name of Medication	CLARITIN
Prophylaxis	Yes ☐ No ☒
Indication	SEASONAL ALLERGIES
Dose per administration	10
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:31

	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)	2 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	No ☒
If not Ongoing, End date (dd MMM yyyy)	3 SEP 2020	
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 ☒	

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:31

Name of Medication	IBUPROFEN
Prophylaxis	Yes ☐ No ☒
Indication	MUSCLE AND JOINT ACHES
Dose per administration	800
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 ☐

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:31

	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)		25 SEP 2020
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)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:31

Name of Medication	COSENTYX
Prophylaxis	Yes ☐ No ☒
Indication	ARTHRITIS
Dose per administration	150
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	
WEEKLY FOR 5 WEEKS AND THEN MONTHLY	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:31

	Intramuscular	☒
	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)		7 OCT 2020
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)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☐

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:31

Name of Medication	PREDNISONE
Prophylaxis	Yes ☐ No ☒
Indication	ARTHRITIS
Dose per administration	TAPER
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	TAPER
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 ☐

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:31

	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)		10 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		15 OCT 2020
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	☒

US3432260

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:23:31

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3432260

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:23:31

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3432260

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:23:31

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 ☐

US3432260

Folder: SAE USA-US078-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:31

SAEID	USA-US078-2020-MRNA-1273-P301000010
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1

US3432260

Folder: SAE USA-US078-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:23:31

SAEID	USA-US078-2020-MRNA-1273-P301000010
Serious	Yes ☒ No ☐
Death	Yes ☐ No ☒
Life threatening	Yes ☐ No ☒
Requires inpatient or prolongation of existing Hospitalization	Yes ☒ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ☒
Congenital anomaly or birth defect	Yes ☐ No ☒
Other medically important event	Yes ☐ No ☒
Investigator's First Name	LINDSEY
Investigator's Last Name	BADEN
Site Address: Street	
Site Address: City	
Site Address: State	MA
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	1
Date of submission (Pre-filled from custom function)	06/NOV/2020 19:03
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3432260 (Prod: Brigham and Womens Hospital)

US3432260

Form: Participant Creation

Generated On: 26 Nov 2020 09:23:31

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3432260'	RWS_ENDPOINT ENDPOINT (b) (4) 	24 Aug 2020 15:54:26

US3432260

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:23:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 16:31:12

US3432260

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '24 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	24 Aug 2020 15:54:27

US3432260

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 16:31:12

US3432260

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:23:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	24 Aug 2020 16:31:12

US3432260

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:31

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered (b) (6) 1975'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	24 Aug 2020 15:54:28

US3432260

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:31

[Age](#)

Audit	User	Time (GMT)
User entered '45'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:28:43

US3432260

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:31

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	24 Aug 2020 18:28:43

US3432260

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:31

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '45'	System	24 Aug 2020 16:31:42

US3432260

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:31

Sex

Audit	User	Time (GMT)
User entered 'Female (F)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:28:43

US3432260

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:31

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:28:43

US3432260

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:31

[White](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:28:43

US3432260

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:31

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:28:43

US3432260

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:31

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:28:43

US3432260

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:31

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:28:43

US3432260

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:31

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:28:43

US3432260

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:31

[Other](#)

Audit	User	Time (GMT)
User entered '1'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:28:43

US3432260

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:31

[If race is Other, specify](#)

Audit	User	Time (GMT)
User entered 'Latin'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:28:43

US3432260

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:31

Unknown

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:28:43

US3432260

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:23:31

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:28:43

US3432260

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 16:31:42

US3432260

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	24 Aug 2020 16:31:42

US3432260

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '2020'	System	24 Aug 2020 16:31:42

US3432260

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:31

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 16:31:42

US3432260

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 16:31:42

US3432260

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 16:31:42

US3432260

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:31

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 16:31:42

US3432260

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:31

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 16:31:42

US3432260

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:31

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	24 Aug 2020 15:54:27

US3432260

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:23:31

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 16:31:48

US3432260

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 16:31:48

US3432260

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:23:31

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:30:28

US3432260

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:31

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Spondyloarthropathies, PT: Spondylitis, LLT: Spondylarthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 09:29:48
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 09:29:48
Data point term sent to Coder	System	24 Aug 2020 18:31:04
User entered 'Spondyloarthritis'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:31:01

US3432260

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:31:01

US3432260

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:31:01

US3432260

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:31:01

US3432260

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:31:01

US3432260

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:31:01

US3432260

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	24 Aug 2020 18:31:01

US3432260

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '2015'	System	24 Aug 2020 18:31:01

US3432260

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 18:31:01

US3432260

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 18:31:01

US3432260

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:31

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Spinal cord and nerve root disorders, HLT: Cervical spinal cord and nerve root disorders, PT: Cervical cord compression, LLT: Cervical cord compression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 21:00:38
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Aug 2020 21:00:38
Data point term sent to Coder	System	24 Aug 2020 18:35:11
User entered 'Cervical compression'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:34:54

US3432260

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:34:54

US3432260

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:34:54

US3432260

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:34:54

US3432260

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:34:54

US3432260

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:34:54

US3432260

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	24 Aug 2020 18:34:54

US3432260

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '2015'	System	24 Aug 2020 18:34:54

US3432260

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 18:34:54

US3432260

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 18:34:54

US3432260

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:31

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 18:36:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 18:36:47
Data point term sent to Coder	System	24 Aug 2020 18:35:12
User entered 'GERD'	Julia Klopfer (b) (4)	24 Aug 2020 18:35:09
	(b) (4)	

US3432260

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'UN UNK 2017'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:35:09

US3432260

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:35:09

US3432260

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:35:09

US3432260

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:35:09

US3432260

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:35:09

US3432260

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	24 Aug 2020 18:35:09

US3432260

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '2017'	System	24 Aug 2020 18:35:09

US3432260

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 18:35:09

US3432260

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 18:35:09

US3432260

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:31

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLG: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine - version MedDRA\23.0.	Coder Import (b) (4)	24 Aug 2020 18:36:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	24 Aug 2020 18:36:48
Data point term sent to Coder	System	24 Aug 2020 18:36:12
User entered 'Migraines'	Julia Klopfer (b) (4)	24 Aug 2020 18:35:27
	(b) (4)	

US3432260

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'UN UNK 2019'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:35:27

US3432260

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:35:27

US3432260

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:35:27

US3432260

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:35:27

US3432260

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:35:27

US3432260

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'Jan 2019'	System	24 Aug 2020 18:35:27

US3432260

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '2019'	System	24 Aug 2020 18:35:27

US3432260

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 18:35:27

US3432260

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 18:35:27

US3432260

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:31

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Chronic sinusitis, LLT: Chronic sinusitis - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 23:58:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 23:58:52
Data point term sent to Coder	System	10 Sep 2020 23:58:20
User entered 'Chronic Sinusitis'	Xhoi Mitre (b) (4)	10 Sep 2020 23:57:22

US3432260

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'UN UNK 1990'	Xhoi Mitre (b) (4) (b) (4)	10 Sep 2020 23:57:22

US3432260

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	10 Sep 2020 23:57:22

US3432260

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	10 Sep 2020 23:57:22

US3432260

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	10 Sep 2020 23:57:22

US3432260

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	10 Sep 2020 23:57:22

US3432260

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	10 Sep 2020 23:57:22

US3432260

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '1990'	System	10 Sep 2020 23:57:22

US3432260

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 23:57:22

US3432260

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 23:57:22

US3432260

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:31

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:58:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 17:58:47
Data point term sent to Coder	System	21 Sep 2020 17:58:06
User entered 'Seasonal Allergies'	(b) (4), (b) (6) (b) (4)	21 Sep 2020 17:57:23

US3432260

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	(b) (4), (b) (6)	21 Sep 2020 17:57:23

US3432260

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Sep 2020 17:57:23

US3432260

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 17:57:23

US3432260

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 17:57:23

US3432260

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	21 Sep 2020 17:57:23

US3432260

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	21 Sep 2020 17:57:23

US3432260

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '2018'	System	21 Sep 2020 17:57:23

US3432260

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 17:57:23

US3432260

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 17:57:23

US3432260

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:31

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Oct 2020 15:49:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Oct 2020 15:49:34
Data point term sent to Coder	System	24 Oct 2020 15:48:47
User entered 'hysterectomy (fibroids)'	(b) (4), (b) (6) (b) (4)	24 Oct 2020 15:48:34

US3432260

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'un UNK 2016'	(b) (4), (b) (6)	24 Oct 2020 15:48:34

US3432260

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Oct 2020 15:48:34

US3432260

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	24 Oct 2020 15:48:34

US3432260

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'un UNK 2016'	(b) (4), (b) (6)	24 Oct 2020 15:48:34

US3432260

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Oct 2020 15:48:34

US3432260

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	24 Oct 2020 15:48:34

US3432260

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '2016'	System	24 Oct 2020 15:48:34

US3432260

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'Jan 2016'	System	24 Oct 2020 15:48:34

US3432260

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '2016'	System	24 Oct 2020 15:48:34

US3432260

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:36:30

US3432260

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:36:30

US3432260

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '11:50'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:36:30

US3432260

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:50'	System	24 Aug 2020 18:36:30

US3432260

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '173' cm	Julia Klopfer (b) (4)	24 Aug 2020 18:36:30
DataPoint set to visible.	(b) (4) System	24 Aug 2020 16:31:48

US3432260

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '73.4' kg	Julia Klopfer (b) (4)	24 Aug 2020 18:36:30
DataPoint set to visible.	(b) (4) System	24 Aug 2020 16:31:48

US3432260

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '24.52471'	System	17 Sep 2020 00:21:16
User entered '24.5'	System	24 Aug 2020 18:36:30
DataPoint set to visible.	System	24 Aug 2020 16:31:48

US3432260

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	24 Aug 2020 18:36:30
DataPoint set to visible.	System	24 Aug 2020 16:31:48

US3432260

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:36:30

US3432260

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

[Route of measurement](#)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:36:30

US3432260

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:36:30

US3432260

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:36:30

US3432260

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	24 Aug 2020 18:36:30

US3432260

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:36:30

US3432260

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	24 Aug 2020 18:36:30

US3432260

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:36:30

US3432260

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Aug 2020 18:36:30

US3432260

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:36:30

US3432260

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Aug 2020 18:36:30

US3432260

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:36:40

US3432260

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:36:40

US3432260

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:37:23

US3432260

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:37:23

US3432260

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:31

If No, what is the reason?

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 05:06:32
Query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' answered with 'will follow up with participant about procedure date and medical condition at next visit' (Site from DM).	Bruce Bausk (b) (4)	21 Oct 2020 23:14:20
User opened query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 06:59:37
User entered 'Surgically sterile (SURGICALLY STERILE)'	Julia Klopfer (b) (4)	24 Aug 2020 18:37:23

US3432260

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:31

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:37:23

US3432260

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'UN UNK 2017'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:37:23

US3432260

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:31

[Date of surgery unknown](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:37:23

US3432260

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:37:23

US3432260

Folder: Screening

Form: Childbearing Potential

Generated On: 26 Nov 2020 09:23:31

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:37:23

US3432260

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:37:52

US3432260

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:37:52

US3432260

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:37:52

US3432260

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:37:52

US3432260

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:37:52

US3432260

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:37:52

US3432260

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:37:52

US3432260

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:37:52

US3432260

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:37:52

US3432260

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:37:52

US3432260

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:37:52

US3432260

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:31

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:37:52

US3432260

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:31

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:37:52

US3432260

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:31

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:37:52

US3432260

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:37:52

US3432260

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:37:52

US3432260

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '1'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:37:52

US3432260

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:37:52

US3432260

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:37:52

US3432260

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:31

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:37:52

US3432260

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:23:31

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:37:52

US3432260

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:23:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:38:05

US3432260

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:38:05

US3432260

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:38:05

US3432260

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:23:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	24 Aug 2020 18:38:05

US3432260

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '24 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	24 Aug 2020 16:20:15

US3432260

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '107801'	RWS_ENDPOINT ENDPOINT (b) (4) 	24 Aug 2020 16:20:15

US3432260

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	24 Aug 2020 16:20:15

US3432260

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:38:17

US3432260

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:38:17

US3432260

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:38:17

US3432260

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:38:17

US3432260

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:31

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:38:17

US3432260

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 21:15:46
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:39:59
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 02:39:24

US3432260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:31

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:40:31

US3432260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:31

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:40:31

US3432260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:31

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:40:31

US3432260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:31

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:40:31

US3432260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:31

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:40:31

US3432260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:40:31

US3432260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:40:31

US3432260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '11:50'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:40:31

US3432260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:50'	System	24 Aug 2020 18:40:31

US3432260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.5' C	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:40:31

US3432260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:31

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:40:31

US3432260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:31

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:40:31

US3432260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '75'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:40:31

US3432260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	24 Aug 2020 18:40:31

US3432260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '14'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:40:31

US3432260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	24 Aug 2020 18:40:31

US3432260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '122'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:40:31

US3432260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Aug 2020 18:40:31

US3432260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '81'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:40:31

US3432260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Aug 2020 18:40:31

US3432260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:31

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:40:31

US3432260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:23:31

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:40:31

US3432260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:31

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:40:31

US3432260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:40:31

US3432260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:40:31

US3432260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '13:18'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:40:31

US3432260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '24 Aug 2020 13:18'	System	24 Aug 2020 18:40:31

US3432260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '37.2' C	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:40:31

US3432260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:31

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:40:31

US3432260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:31

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:40:31

US3432260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '68'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:40:31

US3432260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	24 Aug 2020 18:40:31

US3432260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '16'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:40:31

US3432260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	24 Aug 2020 18:40:31

US3432260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '128'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:40:31

US3432260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Aug 2020 18:40:31

US3432260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '74'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:40:31

US3432260

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Aug 2020 18:40:31

US3432260

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:31

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:40:35

US3432260

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:31

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:40:35

US3432260

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 16:57:29

US3432260

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:31

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 16:57:29

US3432260

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 16:57:29

US3432260

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	24 Aug 2020 16:57:29

US3432260

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 16:57:29

US3432260

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '12:48'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 16:57:29

US3432260

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:48'	System	24 Aug 2020 16:57:29

US3432260

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 16:57:29

US3432260

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:31

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	24 Aug 2020 16:57:29

US3432260

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:23:31

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	24 Aug 2020 16:57:29

US3432260

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:40:57

US3432260

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:40:57

US3432260

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:31

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '12:17'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:40:57

US3432260

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:17'	System	24 Aug 2020 18:40:57

US3432260

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:23:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Aug 2020'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:41:12

US3432260

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:31

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:41:12

US3432260

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:41:12

US3432260

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '12:25'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:41:12

US3432260

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:25'	System	24 Aug 2020 18:41:12

US3432260

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:31

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:41:12

US3432260

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:41:12

US3432260

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:41:12

US3432260

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 18:41:12

US3432260

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:41:16

US3432260

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:23:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 18:41:16

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 16:57:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-24T13:20:31', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'f0c4e1a9-880b-49d0-8091-08b89da5cf83'	System	24 Aug 2020 17:20:49
User entered 'Yes (Y)'	System	24 Aug 2020 17:20:49

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-24T13:20:35', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'f0c4e1a9-880b-49d0-8091-08b89da5cf83'	System	24 Aug 2020 17:20:49
User entered '98.9'	System	24 Aug 2020 17:20:49

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-24T13:20:39', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'f0c4e1a9-880b-49d0-8091-08b89da5cf83'	System	24 Aug 2020 17:20:49
User entered 'No (N)'	System	24 Aug 2020 17:20:49

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-24T13:20:44', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'f0c4e1a9-880b-49d0-8091-08b89da5cf83'	System	24 Aug 2020 17:20:49
User entered '24 Aug 2020 13:20'	System	24 Aug 2020 17:20:49

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 13:08'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 15:38'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 16:57:29
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-24T20:18:42', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'f1fc9429-b4bf-47c5-b8bd-74464e551d42'	System	25 Aug 2020 00:18:59
User entered 'Yes (Y)'	System	25 Aug 2020 00:18:59

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-24T20:18:47', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'f1fc9429-b4bf-47c5-b8bd-74464e551d42'	System	25 Aug 2020 00:18:59
User entered '98.7'	System	25 Aug 2020 00:18:59

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-24T20:18:51', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'f1fc9429-b4bf-47c5-b8bd-74464e551d42'	System	25 Aug 2020 00:18:59
User entered 'No (N)'	System	25 Aug 2020 00:18:59

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-24T20:18:56', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'f1fc9429-b4bf-47c5-b8bd-74464e551d42'	System	25 Aug 2020 00:18:59
User entered '24 Aug 2020 20:18'	System	25 Aug 2020 00:18:59

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 16:33'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 16:57:29
User entered 'Day 2'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-25T16:52:49', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '12301f04-4c68-48c6-b999-24ba684c48ca'	System	25 Aug 2020 20:53:09
User entered 'Yes (Y)'	System	25 Aug 2020 20:53:09

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-25T16:52:54', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '12301f04-4c68-48c6-b999-24ba684c48ca'	System	25 Aug 2020 20:53:09
User entered '98.4'	System	25 Aug 2020 20:53:09

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-25T16:52:57', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '12301f04-4c68-48c6-b999-24ba684c48ca'	System	25 Aug 2020 20:53:09
User entered 'No (N)'	System	25 Aug 2020 20:53:09

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-25T16:53:08', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '12301f04-4c68-48c6-b999-24ba684c48ca'	System	25 Aug 2020 20:53:09
User entered '25 Aug 2020 16:53'	System	25 Aug 2020 20:53:09

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 16:57:29
User entered 'Day 3'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-26T12:14:34', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'd4fc3548-8a76-43d2-9b92-06194eb8fc7d'	System	26 Aug 2020 16:14:50
User entered 'Yes (Y)'	System	26 Aug 2020 16:14:50

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-26T12:14:45', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'd4fc3548-8a76-43d2-9b92-06194eb8fc7d'	System	26 Aug 2020 16:14:50
User entered '97.9'	System	26 Aug 2020 16:14:50

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-26T12:14:42', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'd4fc3548-8a76-43d2-9b92-06194eb8fc7d'	System	26 Aug 2020 16:14:50
User entered 'No (N)'	System	26 Aug 2020 16:14:50

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-26T12:14:47', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'd4fc3548-8a76-43d2-9b92-06194eb8fc7d'	System	26 Aug 2020 16:14:50
User entered '26 Aug 2020 12:14'	System	26 Aug 2020 16:14:50

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 16:57:29
User entered 'Day 4'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-27T16:18:16', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'f74f2d2a-a651-45a2-983c-c2a2fba5b4f2'	System	27 Aug 2020 20:18:45
User entered 'Yes (Y)'	System	27 Aug 2020 20:18:45

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-27T16:18:19', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'f74f2d2a-a651-45a2-983c-c2a2fba5b4f2'	System	27 Aug 2020 20:18:45
User entered '98.7'	System	27 Aug 2020 20:18:45

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-27T16:18:28', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'f74f2d2a-a651-45a2-983c-c2a2fba5b4f2'	System	27 Aug 2020 20:18:45
User entered 'Yes (Y)'	System	27 Aug 2020 20:18:45

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'confirmed' (Site from System).	(b) (4), (b) (6)	03 Nov 2020 06:32:37
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-27T16:18:36', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'f74f2d2a-a651-45a2-983c-c2a2fba5b4f2'	Bruce Bausk (b) (4)	19 Oct 2020 20:38:21
User entered '1'	System	27 Aug 2020 20:18:45

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:31

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-27T16:18:36', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'f74f2d2a-a651-45a2-983c-c2a2fba5b4f2'	System	27 Aug 2020 20:18:45
User entered '0'	System	27 Aug 2020 20:18:45

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-27T16:18:42', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'f74f2d2a-a651-45a2-983c-c2a2fba5b4f2'	System	27 Aug 2020 20:18:45
User entered '27 Aug 2020 16:18'	System	27 Aug 2020 20:18:45

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 16:57:29
User entered 'Day 5'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-28T13:51:46', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '732f4af6-7369-4109-b41a-7afda2d51906'	System	28 Aug 2020 17:52:05
User entered 'Yes (Y)'	System	28 Aug 2020 17:52:05

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-28T13:51:51', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '732f4af6-7369-4109-b41a-7afda2d51906'	System	28 Aug 2020 17:52:05
User entered '98.7'	System	28 Aug 2020 17:52:05

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-28T13:51:58', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '732f4af6-7369-4109-b41a-7afda2d51906'	System	28 Aug 2020 17:52:05
User entered 'No (N)'	System	28 Aug 2020 17:52:05

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-28T13:52:01', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '732f4af6-7369-4109-b41a-7afda2d51906'	System	28 Aug 2020 17:52:05
User entered '28 Aug 2020 13:52'	System	28 Aug 2020 17:52:05

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 16:57:29
User entered 'Day 6'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-29T14:11:47', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '1fcd66e8-da32-42c6-a977-8fccccca7a9ff'	System	29 Aug 2020 18:12:05
User entered 'Yes (Y)'	System	29 Aug 2020 18:12:05

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-29T14:11:52', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '1fcd66e8-da32-42c6-a977-8fccccca7a9ff'	System	29 Aug 2020 18:12:05
User entered '98.6'	System	29 Aug 2020 18:12:05

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-29T14:11:56', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '1fcd66e8-da32-42c6-a977-8fccccca7a9ff'	System	29 Aug 2020 18:12:05
User entered 'No (N)'	System	29 Aug 2020 18:12:05

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-29T14:12:02', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '1fcd66e8-da32-42c6-a977-8fccccca7a9ff'	System	29 Aug 2020 18:12:05
User entered '29 Aug 2020 14:12'	System	29 Aug 2020 18:12:05

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 16:57:29
User entered 'Day 7'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-30T14:18:08', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '6d665707-f507-472a-9e43-cfbbcdc12570'	System	30 Aug 2020 18:18:23
User entered 'Yes (Y)'	System	30 Aug 2020 18:18:23

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-30T14:18:13', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '6d665707-f507-472a-9e43-cfbbcdc12570'	System	30 Aug 2020 18:18:23
User entered '98.4'	System	30 Aug 2020 18:18:23

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-30T14:18:16', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '6d665707-f507-472a-9e43-cfbbc12570'	System	30 Aug 2020 18:18:23
User entered 'No (N)'	System	30 Aug 2020 18:18:23

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-30T14:18:19', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '6d665707-f507-472a-9e43-cfbbcdc12570'	System	30 Aug 2020 18:18:23
User entered '30 Aug 2020 14:18'	System	30 Aug 2020 18:18:23

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 16:57:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-24T13:20:54', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '252370a1-1b5d-4e50-8b38-1bddca44159'	System	24 Aug 2020 17:21:07
User entered 'Does not interfere with activity (2)'	System	24 Aug 2020 17:21:07

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-24T13:20:57', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '252370a1-1b5d-4e50-8b38-1bbddca44159'	System	24 Aug 2020 17:21:07
User entered 'No (N)'	System	24 Aug 2020 17:21:07

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-24T13:20:59', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '252370a1-1b5d-4e50-8b38-1bbddca44159'	System	24 Aug 2020 17:21:07
User entered 'No (N)'	System	24 Aug 2020 17:21:07

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-24T13:21:02', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '252370a1-1b5d-4e50-8b38-1bbddca44159'	System	24 Aug 2020 17:21:07
User entered 'None (1)'	System	24 Aug 2020 17:21:07

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-24T13:21:05', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '252370a1-1b5d-4e50-8b38-1bbddca44159'	System	24 Aug 2020 17:21:07
User entered '24 Aug 2020 13:21'	System	24 Aug 2020 17:21:07

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 13:08'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 15:38'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 16:57:29
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-24T20:19:32', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '41bb04f2-8703-4687-9434-56bace1b28e6'	System	25 Aug 2020 00:20:06
User entered 'None (1)'	System	25 Aug 2020 00:20:06

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-24T20:19:36', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '41bb04f2-8703-4687-9434-56bace1b28e6'	System	25 Aug 2020 00:20:06
User entered 'Yes (Y)'	System	25 Aug 2020 00:20:06

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

Please record - REDNESS AT INJECTION SITE (in mm)

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-24T20:19:49', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '41bb04f2-8703-4687-9434-56bace1b28e6' User entered '1'	System	25 Aug 2020 00:20:06
	System	25 Aug 2020 00:20:06

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-24T20:19:54', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '41bb04f2-8703-4687-9434-56bace1b28e6'	System	25 Aug 2020 00:20:06
User entered 'No (N)'	System	25 Aug 2020 00:20:06

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-24T20:19:58', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '41bb04f2-8703-4687-9434-56bace1b28e6'	System	25 Aug 2020 00:20:06
User entered 'None (1)'	System	25 Aug 2020 00:20:06

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-24T20:20:00', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '41bb04f2-8703-4687-9434-56bace1b28e6'	System	25 Aug 2020 00:20:06
User entered '24 Aug 2020 20:20'	System	25 Aug 2020 00:20:06

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 16:33'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 16:57:29
User entered 'Day 2'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-25T16:53:11', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '4fa256fd-c33b-4c85-84ac-0e9de2d2ad93'	System	25 Aug 2020 20:53:27
User entered 'None (1)'	System	25 Aug 2020 20:53:27

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-25T16:53:14', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '4fa256fd-c33b-4c85-84ac-0e9de2d2ad93'	System	25 Aug 2020 20:53:27
User entered 'No (N)'	System	25 Aug 2020 20:53:27

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-25T16:53:20', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '4fa256fd-c33b-4c85-84ac-0e9de2d2ad93'	System	25 Aug 2020 20:53:27
User entered 'No (N)'	System	25 Aug 2020 20:53:27

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-25T16:53:23', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '4fa256fd-c33b-4c85-84ac-0e9de2d2ad93'	System	25 Aug 2020 20:53:27
User entered 'None (1)'	System	25 Aug 2020 20:53:27

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-25T16:53:26', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '4fa256fd-c33b-4c85-84ac-0e9de2d2ad93'	System	25 Aug 2020 20:53:27
User entered '25 Aug 2020 16:53'	System	25 Aug 2020 20:53:27

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 16:57:29
User entered 'Day 3'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-26T12:14:51', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '1033af95-f110-4bff-9f85-3311bfa2773d'	System	26 Aug 2020 16:15:37
User entered 'None (1)'	System	26 Aug 2020 16:15:37

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-26T12:14:56', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '1033af95-f110-4bff-9f85-3311bfa2773d'	System	26 Aug 2020 16:15:37
User entered 'No (N)'	System	26 Aug 2020 16:15:37

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-26T12:14:59', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '1033af95-f110-4bff-9f85-3311bfa2773d'	System	26 Aug 2020 16:15:37
User entered 'No (N)'	System	26 Aug 2020 16:15:37

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-26T12:15:00', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '1033af95-f110-4bff-9f85-3311bfa2773d'	System	26 Aug 2020 16:15:37
User entered 'None (1)'	System	26 Aug 2020 16:15:37

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-26T12:15:04', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '1033af95-f110-4bff-9f85-3311bfa2773d'	System	26 Aug 2020 16:15:37
User entered '26 Aug 2020 12:15'	System	26 Aug 2020 16:15:37

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 16:57:29
User entered 'Day 4'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-27T16:18:45', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '1ffe567e-0568-40c2-99f4-5a82d0a7c727'	System	27 Aug 2020 20:19:03
User entered 'None (1)'	System	27 Aug 2020 20:19:03

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-27T16:18:52', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '1ffe567e-0568-40c2-99f4-5a82d0a7c727'	System	27 Aug 2020 20:19:03
User entered 'No (N)'	System	27 Aug 2020 20:19:03

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-27T16:18:54', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '1ffe567e-0568-40c2-99f4-5a82d0a7c727'	System	27 Aug 2020 20:19:03
User entered 'No (N)'	System	27 Aug 2020 20:19:03

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-27T16:18:57', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '1ffe567e-0568-40c2-99f4-5a82d0a7c727'	System	27 Aug 2020 20:19:03
User entered 'None (1)'	System	27 Aug 2020 20:19:03

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-27T16:19:00', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '1ffe567e-0568-40c2-99f4-5a82d0a7c727'	System	27 Aug 2020 20:19:03
User entered '27 Aug 2020 16:19'	System	27 Aug 2020 20:19:03

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 16:57:29
User entered 'Day 5'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-28T13:52:04', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '12c32256-806e-45e9-a926-7caece39271e'	System	28 Aug 2020 17:52:18
User entered 'None (1)'	System	28 Aug 2020 17:52:18

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-28T13:52:07', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '12c32256-806e-45e9-a926-7caece39271e'	System	28 Aug 2020 17:52:18
User entered 'No (N)'	System	28 Aug 2020 17:52:18

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-28T13:52:10', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '12c32256-806e-45e9-a926-7caece39271e'	System	28 Aug 2020 17:52:18
User entered 'No (N)'	System	28 Aug 2020 17:52:18

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-28T13:52:12', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '12c32256-806e-45e9-a926-7caece39271e' User entered 'None (1)'	System	28 Aug 2020 17:52:18

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-28T13:52:13', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '12c32256-806e-45e9-a926-7caece39271e' User entered '28 Aug 2020 13:52'	System	28 Aug 2020 17:52:18
	System	28 Aug 2020 17:52:18

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 16:57:29
User entered 'Day 6'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-29T14:12:06', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '4748070a-4a2c-491a-8bd5-433a83b32d45'	System	29 Aug 2020 18:12:18
User entered 'None (1)'	System	29 Aug 2020 18:12:18

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-29T14:12:09', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '4748070a-4a2c-491a-8bd5-433a83b32d45'	System	29 Aug 2020 18:12:18
User entered 'No (N)'	System	29 Aug 2020 18:12:18

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-29T14:12:12', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '4748070a-4a2c-491a-8bd5-433a83b32d45'	System	29 Aug 2020 18:12:18
User entered 'No (N)'	System	29 Aug 2020 18:12:18

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-29T14:12:14', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '4748070a-4a2c-491a-8bd5-433a83b32d45'	System	29 Aug 2020 18:12:18
User entered 'None (1)'	System	29 Aug 2020 18:12:18

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-29T14:12:16', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '4748070a-4a2c-491a-8bd5-433a83b32d45'	System	29 Aug 2020 18:12:18
User entered '29 Aug 2020 14:12'	System	29 Aug 2020 18:12:18

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 16:57:29
User entered 'Day 7'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:31

[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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-30T14:18:32', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '62cabab9-2ec5-4992-8fd9-18f32ce55d9f'	System	30 Aug 2020 18:18:49
User entered 'None (1)'	System	30 Aug 2020 18:18:49

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-30T14:18:36', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '62cabab9-2ec5-4992-8fd9-18f32ce55d9f'	System	30 Aug 2020 18:18:49
User entered 'No (N)'	System	30 Aug 2020 18:18:49

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-30T14:18:38', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '62cabab9-2ec5-4992-8fd9-18f32ce55d9f'	System	30 Aug 2020 18:18:49
User entered 'No (N)'	System	30 Aug 2020 18:18:49

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-30T14:18:41', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '62cabab9-2ec5-4992-8fd9-18f32ce55d9f'	System	30 Aug 2020 18:18:49
User entered 'None (1)'	System	30 Aug 2020 18:18:49

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-30T14:18:45', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '62cabab9-2ec5-4992-8fd9-18f32ce55d9f' User entered '30 Aug 2020 14:18'	System	30 Aug 2020 18:18:49
	System	30 Aug 2020 18:18:49

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 16:57:29
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-24T13:21:09', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '6ee6b5f2-5161-4a9f-9dd9-998f13f2f435'	System	24 Aug 2020 17:21:33
User entered 'None (0)'	System	24 Aug 2020 17:21:33

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-24T13:21:11', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '6ee6b5f2-5161-4a9f-9dd9-998f13f2f435'	System	24 Aug 2020 17:21:33
User entered 'None (0)'	System	24 Aug 2020 17:21:33

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-24T13:21:14', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '6ee6b5f2-5161-4a9f-9dd9-998f13f2f435'	System	24 Aug 2020 17:21:33
User entered 'None (0)'	System	24 Aug 2020 17:21:33

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-24T13:21:16', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '6ee6b5f2-5161-4a9f-9dd9-998f13f2f435'	System	24 Aug 2020 17:21:33
User entered 'None (0)'	System	24 Aug 2020 17:21:33

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-24T13:21:18', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '6ee6b5f2-5161-4a9f-9dd9-998f13f2f435'	System	24 Aug 2020 17:21:33
User entered 'None (0)'	System	24 Aug 2020 17:21:33

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-24T13:21:20', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '6ee6b5f2-5161-4a9f-9dd9-998f13f2f435'	System	24 Aug 2020 17:21:33
User entered 'None (0)'	System	24 Aug 2020 17:21:33

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-24T13:21:29', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '6ee6b5f2-5161-4a9f-9dd9-998f13f2f435'	System	24 Aug 2020 17:21:33
User entered 'No (N)'	System	24 Aug 2020 17:21:33

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-24T13:21:31', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '6ee6b5f2-5161-4a9f-9dd9-998f13f2f435'	System	24 Aug 2020 17:21:33
User entered '24 Aug 2020 13:21'	System	24 Aug 2020 17:21:33

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 13:08'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 15:38'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 16:57:29
User entered 'Day 1, after vaccination (at home)'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-24T20:19:09', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'fd414df0-9fb9-464f-8571-a335e2a309d9'	System	25 Aug 2020 00:19:30
User entered 'No interference with activity (1)'	System	25 Aug 2020 00:19:30

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-24T20:19:12', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'fd414df0-9fb9-464f-8571-a335e2a309d9'	System	25 Aug 2020 00:19:30
User entered 'None (0)'	System	25 Aug 2020 00:19:30

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-24T20:19:15', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'fd414df0-9fb9-464f-8571-a335e2a309d9'	System	25 Aug 2020 00:19:30
User entered 'None (0)'	System	25 Aug 2020 00:19:30

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-24T20:19:17', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'fd414df0-9fb9-464f-8571-a335e2a309d9'	System	25 Aug 2020 00:19:30
User entered 'None (0)'	System	25 Aug 2020 00:19:30

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-24T20:19:20', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'fd414df0-9fb9-464f-8571-a335e2a309d9'	System	25 Aug 2020 00:19:30
User entered 'None (0)'	System	25 Aug 2020 00:19:30

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-24T20:19:22', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'fd414df0-9fb9-464f-8571-a335e2a309d9'	System	25 Aug 2020 00:19:30
User entered 'None (0)'	System	25 Aug 2020 00:19:30

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-24T20:19:25', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'fd414df0-9fb9-464f-8571-a335e2a309d9'	System	25 Aug 2020 00:19:30
User entered 'No (N)'	System	25 Aug 2020 00:19:30

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-24T20:19:28', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'fd414df0-9fb9-464f-8571-a335e2a309d9'	System	25 Aug 2020 00:19:30
User entered '24 Aug 2020 20:19'	System	25 Aug 2020 00:19:30

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 16:33'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 16:57:29
User entered 'Day 2'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-25T16:53:31', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'db8cb027-5e33-4fb6-9bf2-44a12a04668a'	System	25 Aug 2020 20:53:59
User entered 'No interference with activity (1)'	System	25 Aug 2020 20:53:59

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-25T16:53:35', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'db8cb027-5e33-4fb6-9bf2-44a12a04668a'	System	25 Aug 2020 20:53:59
User entered 'No interference with activity (1)'	System	25 Aug 2020 20:53:59

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-25T16:53:37', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'db8cb027-5e33-4fb6-9bf2-44a12a04668a'	System	25 Aug 2020 20:53:59
User entered 'None (0)'	System	25 Aug 2020 20:53:59

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-25T16:53:39', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'db8cb027-5e33-4fb6-9bf2-44a12a04668a'	System	25 Aug 2020 20:53:59
User entered 'None (0)'	System	25 Aug 2020 20:53:59

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-25T16:53:45', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'db8cb027-5e33-4fb6-9bf2-44a12a04668a'	System	25 Aug 2020 20:53:59
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	25 Aug 2020 20:53:59

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-25T16:53:48', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'db8cb027-5e33-4fb6-9bf2-44a12a04668a' User entered 'None (0)'	System	25 Aug 2020 20:53:59
	System	25 Aug 2020 20:53:59

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-25T16:53:52', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'db8cb027-5e33-4fb6-9bf2-44a12a04668a'	System	25 Aug 2020 20:53:59
User entered 'No (N)'	System	25 Aug 2020 20:53:59

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-25T16:53:55', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'db8cb027-5e33-4fb6-9bf2-44a12a04668a'	System	25 Aug 2020 20:53:59
User entered '25 Aug 2020 16:53'	System	25 Aug 2020 20:53:59

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 16:57:29
User entered 'Day 3'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-26T12:15:11', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '96e7c0f1-d59a-44a2-a6ba-d6ded0d047f3'	System	26 Aug 2020 16:15:44
User entered 'No interference with activity (1)'	System	26 Aug 2020 16:15:44

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-26T12:15:14', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '96e7c0f1-d59a-44a2-a6ba-d6ded0d047f3'	System	26 Aug 2020 16:15:44
User entered 'No interference with activity (1)'	System	26 Aug 2020 16:15:44

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-26T12:15:17', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '96e7c0f1-d59a-44a2-a6ba-d6ded0d047f3'	System	26 Aug 2020 16:15:44
User entered 'None (0)'	System	26 Aug 2020 16:15:44

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-26T12:15:21', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '96e7c0f1-d59a-44a2-a6ba-d6ded0d047f3'	System	26 Aug 2020 16:15:44
User entered 'None (0)'	System	26 Aug 2020 16:15:44

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-26T12:15:26', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '96e7c0f1-d59a-44a2-a6ba-d6ded0d047f3'	System	26 Aug 2020 16:15:44
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	26 Aug 2020 16:15:44

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-26T12:15:29', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '96e7c0f1-d59a-44a2-a6ba-d6ded0d047f3'	System	26 Aug 2020 16:15:44
User entered 'None (0)'	System	26 Aug 2020 16:15:44

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-26T12:15:32', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '96e7c0f1-d59a-44a2-a6ba-d6ded0d047f3'	System	26 Aug 2020 16:15:44
User entered 'No (N)'	System	26 Aug 2020 16:15:44

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-26T12:15:34', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '96e7c0f1-d59a-44a2-a6ba-d6ded0d047f3'	System	26 Aug 2020 16:15:44
User entered '26 Aug 2020 12:15'	System	26 Aug 2020 16:15:44

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 16:57:29
User entered 'Day 4'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-27T16:19:05', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '98d423c8-90c0-474b-9bec-1db828a439f8'	System	27 Aug 2020 20:19:27
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	27 Aug 2020 20:19:27

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-27T16:19:08', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '98d423c8-90c0-474b-9bec-1db828a439f8'	System	27 Aug 2020 20:19:27
User entered 'Some interference with activity (2)'	System	27 Aug 2020 20:19:27

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-27T16:19:11', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '98d423c8-90c0-474b-9bec-1db828a439f8'	System	27 Aug 2020 20:19:27
User entered 'None (0)'	System	27 Aug 2020 20:19:27

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-27T16:19:13', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '98d423c8-90c0-474b-9bec-1db828a439f8'	System	27 Aug 2020 20:19:27
User entered 'None (0)'	System	27 Aug 2020 20:19:27

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-27T16:19:18', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '98d423c8-90c0-474b-9bec-1db828a439f8'	System	27 Aug 2020 20:19:27
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	27 Aug 2020 20:19:27

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-27T16:19:20', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '98d423c8-90c0-474b-9bec-1db828a439f8'	System	27 Aug 2020 20:19:27
User entered 'None (0)'	System	27 Aug 2020 20:19:27

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-27T16:19:23', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '98d423c8-90c0-474b-9bec-1db828a439f8'	System	27 Aug 2020 20:19:27
User entered 'No (N)'	System	27 Aug 2020 20:19:27

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-27T16:19:25', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '98d423c8-90c0-474b-9bec-1db828a439f8'	System	27 Aug 2020 20:19:27
User entered '27 Aug 2020 16:19'	System	27 Aug 2020 20:19:27

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 12:00'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 11:59'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 16:57:29
User entered 'Day 5'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-28T13:52:20', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '9beafe63-17b3-43d9-8168-8687df5d7311'	System	28 Aug 2020 17:52:48
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	28 Aug 2020 17:52:48

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-28T13:52:28', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '9beafe63-17b3-43d9-8168-8687df5d7311'	System	28 Aug 2020 17:52:48
User entered 'Some interference with activity (2)'	System	28 Aug 2020 17:52:48

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-28T13:52:31', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '9beafe63-17b3-43d9-8168-8687df5d7311'	System	28 Aug 2020 17:52:48
User entered 'No interference with activity (1)'	System	28 Aug 2020 17:52:48

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-28T13:52:34', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '9beafe63-17b3-43d9-8168-8687df5d7311'	System	28 Aug 2020 17:52:48
User entered 'None (0)'	System	28 Aug 2020 17:52:48

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-28T13:52:37', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '9beafe63-17b3-43d9-8168-8687df5d7311'	System	28 Aug 2020 17:52:48
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	28 Aug 2020 17:52:48

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-28T13:52:40', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '9beafe63-17b3-43d9-8168-8687df5d7311'	System	28 Aug 2020 17:52:48
User entered 'No interference with activity (1)'	System	28 Aug 2020 17:52:48

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-28T13:52:43', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '9beafe63-17b3-43d9-8168-8687df5d7311'	System	28 Aug 2020 17:52:48
User entered 'No (N)'	System	28 Aug 2020 17:52:48

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-28T13:52:45', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '9beafe63-17b3-43d9-8168-8687df5d7311'	System	28 Aug 2020 17:52:48
User entered '28 Aug 2020 13:52'	System	28 Aug 2020 17:52:48

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Aug 2020 12:00'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 11:59'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 16:57:29
User entered 'Day 6'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-29T14:12:21', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '965ba6d4-9261-455f-a6e8-450247c792a8'	System	29 Aug 2020 18:12:55
User entered 'No interference with activity (1)'	System	29 Aug 2020 18:12:55

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-29T14:12:26', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '965ba6d4-9261-455f-a6e8-450247c792a8'	System	29 Aug 2020 18:12:55
User entered 'Some interference with activity (2)'	System	29 Aug 2020 18:12:55

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-29T14:12:28', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '965ba6d4-9261-455f-a6e8-450247c792a8'	System	29 Aug 2020 18:12:55
User entered 'None (0)'	System	29 Aug 2020 18:12:55

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-29T14:12:31', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '965ba6d4-9261-455f-a6e8-450247c792a8' User entered 'None (0)'	System	29 Aug 2020 18:12:55
	System	29 Aug 2020 18:12:55

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-29T14:12:40', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '965ba6d4-9261-455f-a6e8-450247c792a8'	System	29 Aug 2020 18:12:55
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	29 Aug 2020 18:12:55

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-29T14:12:45', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '965ba6d4-9261-455f-a6e8-450247c792a8'	System	29 Aug 2020 18:12:55
User entered 'No interference with activity (1)'	System	29 Aug 2020 18:12:55

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-29T14:12:49', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '965ba6d4-9261-455f-a6e8-450247c792a8'	System	29 Aug 2020 18:12:55
User entered 'No (N)'	System	29 Aug 2020 18:12:55

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-29T14:12:51', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '965ba6d4-9261-455f-a6e8-450247c792a8'	System	29 Aug 2020 18:12:55
User entered '29 Aug 2020 14:12'	System	29 Aug 2020 18:12:55

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Aug 2020 12:00'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 11:59'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 16:57:29
User entered 'Day 7'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-30T14:19:06', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'f3a9ee04-7c06-4f25-bf51-4b646ea0ff01'	System	30 Aug 2020 18:19:31
User entered 'No interference with activity (1)'	System	30 Aug 2020 18:19:31

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-30T14:19:09', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'f3a9ee04-7c06-4f25-bf51-4b646ea0ff01'	System	30 Aug 2020 18:19:31
User entered 'No interference with activity (1)'	System	30 Aug 2020 18:19:31

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-30T14:19:14', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'f3a9ee04-7c06-4f25-bf51-4b646ea0ff01'	System	30 Aug 2020 18:19:31
User entered 'None (0)'	System	30 Aug 2020 18:19:31

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-30T14:19:17', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'f3a9ee04-7c06-4f25-bf51-4b646ea0ff01'	System	30 Aug 2020 18:19:31
User entered 'No interference with activity (1)'	System	30 Aug 2020 18:19:31

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-30T14:19:20', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'f3a9ee04-7c06-4f25-bf51-4b646ea0ff01'	System	30 Aug 2020 18:19:31
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	30 Aug 2020 18:19:31

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-30T14:19:22', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'f3a9ee04-7c06-4f25-bf51-4b646ea0ff01'	System	30 Aug 2020 18:19:31
User entered 'None (0)'	System	30 Aug 2020 18:19:31

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-30T14:19:25', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'f3a9ee04-7c06-4f25-bf51-4b646ea0ff01'	System	30 Aug 2020 18:19:31
User entered 'No (N)'	System	30 Aug 2020 18:19:31

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-30T14:19:27', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'f3a9ee04-7c06-4f25-bf51-4b646ea0ff01'	System	30 Aug 2020 18:19:31
User entered '30 Aug 2020 14:19'	System	30 Aug 2020 18:19:31

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Aug 2020 12:00'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 11:59'	System	24 Aug 2020 16:57:29

US3432260

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 18:12:55
User entered 'Day 8'	System	29 Aug 2020 18:12:55

US3432260

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-31T16:23:06', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'a9adce77-f7d8-4ce4-b8c2-3ad81521980f'	System	31 Aug 2020 20:26:00
User entered 'No interference with activity (1)'	System	31 Aug 2020 20:26:00

US3432260

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-31T16:23:10', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'a9adce77-f7d8-4ce4-b8c2-3ad81521980f'	System	31 Aug 2020 20:26:00
User entered '31 Aug 2020 16:23'	System	31 Aug 2020 20:26:00

US3432260

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 18:12:55

US3432260

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 18:12:55

US3432260

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Aug 2020 18:19:31
User entered 'Day 9'	System	30 Aug 2020 18:19:31

US3432260

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-01T18:09:38', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'ae26bb37-fa09-4b45-a391-d79357b1566f'	System	01 Sep 2020 22:09:46
User entered 'No interference with activity (1)'	System	01 Sep 2020 22:09:46

US3432260

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-01T18:09:41', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'ae26bb37-fa09-4b45-a391-d79357b1566f'	System	01 Sep 2020 22:09:46
User entered '01 Sep 2020 18:09'	System	01 Sep 2020 22:09:46

US3432260

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	30 Aug 2020 18:19:31

US3432260

Folder: Diary Dose 1 (1)

Form: Headache_Day(9)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	30 Aug 2020 18:19:31

US3432260

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 20:26:00
User entered 'Day 10'	System	31 Aug 2020 20:26:00

US3432260

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-02T12:00:19', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '893dda8f-b1bb-41b9-ae9b-9a979c43c600'	System	02 Sep 2020 16:00:40
User entered 'No interference with activity (1)'	System	02 Sep 2020 16:00:40

US3432260

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-02T12:00:21', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '893dda8f-b1bb-41b9-ae9b-9a979c43c600'	System	02 Sep 2020 16:00:40
User entered '02 Sep 2020 12:00'	System	02 Sep 2020 16:00:40

US3432260

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 20:26:00

US3432260

Folder: Diary Dose 1 (1)

Form: Headache_Day(10)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 20:26:00

US3432260

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 22:09:46
User entered 'Day 11'	System	01 Sep 2020 22:09:46

US3432260

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-03T12:06:10', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'd4d9d0f9-fb69-4769-8012-f523efbb467c'	System	03 Sep 2020 16:07:40
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	03 Sep 2020 16:07:40

US3432260

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-03T12:06:13', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'd4d9d0f9-fb69-4769-8012-f523efbb467c'	System	03 Sep 2020 16:07:40
User entered '03 Sep 2020 12:06'	System	03 Sep 2020 16:07:40

US3432260

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 22:09:46

US3432260

Folder: Diary Dose 1 (1)

Form: Headache_Day(11)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 22:09:46

US3432260

Folder: Diary Dose 1 (1)

Form: Headache_Day(12)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	02 Sep 2020 16:00:40
User entered 'Day 12'	System	02 Sep 2020 16:00:40

US3432260

Folder: Diary Dose 1 (1)

Form: Headache_Day(12)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-04T12:01:17', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'ac51751c-4d72-421e-9f89-8195fda580d5'	System	04 Sep 2020 16:02:28
User entered 'No interference with activity (1)'	System	04 Sep 2020 16:02:28

US3432260

Folder: Diary Dose 1 (1)

Form: Headache_Day(12)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-04T12:01:19', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'ac51751c-4d72-421e-9f89-8195fda580d5'	System	04 Sep 2020 16:02:28
User entered '04 Sep 2020 12:01'	System	04 Sep 2020 16:02:28

US3432260

Folder: Diary Dose 1 (1)

Form: Headache_Day(12)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 16:00:40

US3432260

Folder: Diary Dose 1 (1)

Form: Headache_Day(12)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 16:00:40

US3432260

Folder: Diary Dose 1 (1)

Form: Headache_Day(13)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 16:07:40
User entered 'Day 13'	System	03 Sep 2020 16:07:40

US3432260

Folder: Diary Dose 1 (1)

Form: Headache_Day(13)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-05T15:28:41', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'ea7a1ee5-631d-4446-9dbf-7f0ec2a2d721'	System	05 Sep 2020 19:28:45
User entered 'None (0)'	System	05 Sep 2020 19:28:45

US3432260

Folder: Diary Dose 1 (1)

Form: Headache_Day(13)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-05T15:28:43', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'ea7a1ee5-631d-4446-9dbf-7f0ec2a2d721'	System	05 Sep 2020 19:28:45
User entered '05 Sep 2020 15:28'	System	05 Sep 2020 19:28:45

US3432260

Folder: Diary Dose 1 (1)

Form: Headache_Day(13)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 16:07:40

US3432260

Folder: Diary Dose 1 (1)

Form: Headache_Day(13)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 16:07:40

US3432260

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 18:12:55
User entered 'Day 8'	System	29 Aug 2020 18:12:55

US3432260

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-31T16:23:19', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '330614d9-6e11-434a-9666-eb98ce804729'	System	31 Aug 2020 20:26:16
User entered 'Some interference with activity (2)'	System	31 Aug 2020 20:26:16

US3432260

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-31T16:23:22', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '330614d9-6e11-434a-9666-eb98ce804729'	System	31 Aug 2020 20:26:16
User entered '31 Aug 2020 16:23'	System	31 Aug 2020 20:26:16

US3432260

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 18:12:55

US3432260

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 18:12:55

US3432260

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Aug 2020 18:19:31
User entered 'Day 9'	System	30 Aug 2020 18:19:31

US3432260

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-01T18:09:50', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '13c537d6-32c1-46e0-a53a-826ec514b246'	System	01 Sep 2020 22:09:58
User entered 'No interference with activity (1)'	System	01 Sep 2020 22:09:58

US3432260

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-01T18:09:54', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '13c537d6-32c1-46e0-a53a-826ec514b246'	System	01 Sep 2020 22:09:58
User entered '01 Sep 2020 18:09'	System	01 Sep 2020 22:09:58

US3432260

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	30 Aug 2020 18:19:31

US3432260

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(9)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	30 Aug 2020 18:19:31

US3432260

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 20:26:16
User entered 'Day 10'	System	31 Aug 2020 20:26:16

US3432260

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-02T12:00:26', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '97664b5a-1486-40a5-9df2-0db92858f605'	System	02 Sep 2020 16:00:46
User entered 'No interference with activity (1)'	System	02 Sep 2020 16:00:46

US3432260

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-02T12:00:30', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '97664b5a-1486-40a5-9df2-0db92858f605'	System	02 Sep 2020 16:00:46
User entered '02 Sep 2020 12:00'	System	02 Sep 2020 16:00:46

US3432260

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 20:26:16

US3432260

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(10)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 20:26:16

US3432260

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 22:09:58
User entered 'Day 11'	System	01 Sep 2020 22:09:58

US3432260

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-03T12:06:20', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'cc5499d1-430f-42c7-97a8-18fd63d8c938'	System	03 Sep 2020 16:07:46
User entered 'None (0)'	System	03 Sep 2020 16:07:46

US3432260

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-03T12:06:22', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'cc5499d1-430f-42c7-97a8-18fd63d8c938'	System	03 Sep 2020 16:07:46
User entered '03 Sep 2020 12:06'	System	03 Sep 2020 16:07:46

US3432260

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 22:09:58

US3432260

Folder: Diary Dose 1 (1)

Form: Fatigue_Day(11)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 22:09:58

US3432260

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Aug 2020 18:19:31
User entered 'Day 8'	System	30 Aug 2020 18:19:31

US3432260

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:23:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-31T16:23:26', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '39f9a92d-566d-42c3-a62d-16b8dea53289'	System	31 Aug 2020 20:26:29
User entered 'None (0)'	System	31 Aug 2020 20:26:29

US3432260

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-31T16:23:28', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '39f9a92d-566d-42c3-a62d-16b8dea53289'	System	31 Aug 2020 20:26:29
User entered '31 Aug 2020 16:23'	System	31 Aug 2020 20:26:29

US3432260

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	30 Aug 2020 18:19:31

US3432260

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	30 Aug 2020 18:19:31

US3432260

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 18:12:55
User entered 'Day 8'	System	29 Aug 2020 18:12:55

US3432260

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 09:23:31

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-31T16:23:31', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'ec3793d8-8fd1-405a-b70c-90ea4c16a879'	System	31 Aug 2020 20:26:43
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	31 Aug 2020 20:26:43

US3432260

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-31T16:23:35', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'ec3793d8-8fd1-405a-b70c-90ea4c16a879'	System	31 Aug 2020 20:26:43
User entered '31 Aug 2020 16:23'	System	31 Aug 2020 20:26:43

US3432260

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 18:12:55

US3432260

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 18:12:55

US3432260

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Aug 2020 18:19:31
User entered 'Day 9'	System	30 Aug 2020 18:19:31

US3432260

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 26 Nov 2020 09:23:31

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-01T18:09:58', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'd082ef76-008b-4ce4-a87f-42f65196bc51'	System	01 Sep 2020 22:10:03
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	01 Sep 2020 22:10:03

US3432260

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-01T18:10:00', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'd082ef76-008b-4ce4-a87f-42f65196bc51'	System	01 Sep 2020 22:10:03
User entered '01 Sep 2020 18:10'	System	01 Sep 2020 22:10:03

US3432260

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	30 Aug 2020 18:19:31

US3432260

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	30 Aug 2020 18:19:31

US3432260

Folder: Diary Dose 1 (1)

Form: Nausea_Day(10)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 20:26:43
User entered 'Day 10'	System	31 Aug 2020 20:26:43

US3432260

Folder: Diary Dose 1 (1)

Form: Nausea_Day(10)

Generated On: 26 Nov 2020 09:23:31

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-02T12:23:21', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'b0783009-6874-41a3-8f4e-5de9929b9ef5'	System	02 Sep 2020 16:23:25
User entered 'None (0)'	System	02 Sep 2020 16:23:25

US3432260

Folder: Diary Dose 1 (1)

Form: Nausea_Day(10)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-02T12:23:24', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'b0783009-6874-41a3-8f4e-5de9929b9ef5'	System	02 Sep 2020 16:23:25
User entered '02 Sep 2020 12:23'	System	02 Sep 2020 16:23:25

US3432260

Folder: Diary Dose 1 (1)

Form: Nausea_Day(10)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 20:26:43

US3432260

Folder: Diary Dose 1 (1)

Form: Nausea_Day(10)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 20:26:43

US3432260

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Aug 2020 18:12:55
User entered 'Day 8'	System	29 Aug 2020 18:12:55

US3432260

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-31T16:23:41', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'b60e0fef-3572-416a-a072-dac92683538c'	System	31 Aug 2020 20:26:53
User entered 'No (N)'	System	31 Aug 2020 20:26:53

US3432260

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-08-31T16:23:46', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'b60e0fef-3572-416a-a072-dac92683538c'	System	31 Aug 2020 20:26:53
User entered '31 Aug 2020 16:23'	System	31 Aug 2020 20:26:53

US3432260

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '31 Aug 2020 12:00'	System	29 Aug 2020 18:12:55

US3432260

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 11:59'	System	29 Aug 2020 18:12:55

US3432260

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Aug 2020 18:19:31
User entered 'Day 9'	System	30 Aug 2020 18:19:31

US3432260

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-01T18:10:04', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '8c7d816b-53b5-421f-bd6d-bdd2bc4c211e'	System	01 Sep 2020 22:10:08
User entered 'No (N)'	System	01 Sep 2020 22:10:08

US3432260

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-01T18:10:06', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '8c7d816b-53b5-421f-bd6d-bdd2bc4c211e'	System	01 Sep 2020 22:10:08
User entered '01 Sep 2020 18:10'	System	01 Sep 2020 22:10:08

US3432260

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020 12:00'	System	30 Aug 2020 18:19:31

US3432260

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 11:59'	System	30 Aug 2020 18:19:31

US3432260

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	31 Aug 2020 20:26:00
User entered 'Day 10'	System	31 Aug 2020 20:26:00

US3432260

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-02T12:23:27', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '5cac4ab5-5d81-4613-ad58-10c0739ecfbc'	System	02 Sep 2020 16:23:34
User entered 'No (N)'	System	02 Sep 2020 16:23:34

US3432260

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-02T12:23:30', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '5cac4ab5-5d81-4613-ad58-10c0739ecfbc'	System	02 Sep 2020 16:23:34
User entered '02 Sep 2020 12:23'	System	02 Sep 2020 16:23:34

US3432260

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 20:26:00

US3432260

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 20:26:00

US3432260

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Sep 2020 22:09:46
User entered 'Day 11'	System	01 Sep 2020 22:09:46

US3432260

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-03T12:06:28', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'e0ac7cbd-b1d8-4860-a5b8-a89dc7438459'	System	03 Sep 2020 16:07:49
User entered 'No (N)'	System	03 Sep 2020 16:07:49

US3432260

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-03T12:06:30', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'e0ac7cbd-b1d8-4860-a5b8-a89dc7438459'	System	03 Sep 2020 16:07:49
User entered '03 Sep 2020 12:06'	System	03 Sep 2020 16:07:49

US3432260

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 22:09:46

US3432260

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 22:09:46

US3432260

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Sep 2020 16:07:40
User entered 'Day 13'	System	03 Sep 2020 16:07:40

US3432260

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-05T15:28:52', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '343fbd3e-97d5-42e9-a3b3-d74b52ae6095'	System	05 Sep 2020 19:29:01
User entered 'Yes (Y)'	System	05 Sep 2020 19:29:01

US3432260

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-05T15:28:57', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '343fbd3e-97d5-42e9-a3b3-d74b52ae6095'	System	05 Sep 2020 19:29:01
User entered '05 Sep 2020 15:28'	System	05 Sep 2020 19:29:01

US3432260

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Sep 2020 12:00'	System	03 Sep 2020 16:07:40

US3432260

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Sep 2020 11:59'	System	03 Sep 2020 16:07:40

US3432260

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 22:32:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Sep 2020 22:32:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Jun Bai Park Chang (b) (4)	15 Sep 2020 22:32:17
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 13:40:17
User entered empty.	Phoebe Cunningham (b) (4)	01 Sep 2020 13:40:17

US3432260

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '01 Sep 2020' reason for change: Data Entry Error	Jun Bai Park Chang	15 Sep 2020 22:32:17
	(b) (4)	
User entered empty.	Phoebe Cunningham	01 Sep 2020 13:40:17
	(b) (4)	

US3432260

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Jun Bai Park Chang	15 Sep 2020 22:32:17
reason for change: Data Entry Error	(b) (4)	
User entered empty.	Phoebe Cunningham	01 Sep 2020 13:40:17
	(b) (4)	

US3432260

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	01 Sep 2020 13:40:17

US3432260

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Cauley (b) (4) (b) (4)	07 Sep 2020 16:13:14

US3432260

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Sep 2020 16:13:14

US3432260

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	10 Sep 2020 15:00:35

US3432260

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '7 Sep 2020'	Phoebe Cunningham (b) (4)	10 Sep 2020 15:00:35

US3432260

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	10 Sep 2020 15:00:35

US3432260

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	10 Sep 2020 15:00:35

US3432260

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	10 Sep 2020 14:59:50

US3432260

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 14:59:50

US3432260

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Sep 2020 18:22:11

US3432260

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '14 Sep 2020'	(b) (4), (b) (6)	14 Sep 2020 18:22:11

US3432260

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	14 Sep 2020 18:22:11

US3432260

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	14 Sep 2020 18:22:11

US3432260

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 16:54:40

US3432260

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 16:54:40

US3432260

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 17:43:27

US3432260

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 17:43:27

US3432260

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	21 Sep 2020 17:43:27

US3432260

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	21 Sep 2020 17:43:27

US3432260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:31

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	21 Sep 2020 17:47:43

US3432260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 17:47:43

US3432260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 17:47:43

US3432260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '11:16'	(b) (4), (b) (6)	21 Sep 2020 17:47:43

US3432260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:16'	System	21 Sep 2020 17:47:43

US3432260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '99.0' F	(b) (4), (b) (6)	21 Sep 2020 17:47:43

US3432260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:31

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	21 Sep 2020 17:47:43

US3432260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:31

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 17:47:43

US3432260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '71'	(b) (4), (b) (6)	21 Sep 2020 17:47:43

US3432260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Sep 2020 17:47:43

US3432260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '14'	(b) (4), (b) (6)	21 Sep 2020 17:47:43

US3432260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Sep 2020 17:47:43

US3432260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '122'	(b) (4), (b) (6)	21 Sep 2020 17:47:43

US3432260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Sep 2020 17:47:43

US3432260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '83'	(b) (4), (b) (6)	21 Sep 2020 17:47:43

US3432260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:23:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Sep 2020 17:47:43

US3432260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:31

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	21 Sep 2020 17:47:43

US3432260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 17:47:43

US3432260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 17:47:43

US3432260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '12:51'	(b) (4), (b) (6)	21 Sep 2020 17:47:43

US3432260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:51'	System	21 Sep 2020 17:47:43

US3432260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.4' F	(b) (4), (b) (6)	21 Sep 2020 17:47:43

US3432260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:31

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	21 Sep 2020 17:47:43

US3432260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:31

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 17:47:43

US3432260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '74'	(b) (4), (b) (6)	21 Sep 2020 17:47:43

US3432260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Sep 2020 17:47:43

US3432260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '16'	(b) (4), (b) (6)	21 Sep 2020 17:47:43

US3432260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Sep 2020 17:47:43

US3432260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '130'	(b) (4), (b) (6)	21 Sep 2020 17:47:43

US3432260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Sep 2020 17:47:43

US3432260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '78'	(b) (4), (b) (6)	21 Sep 2020 17:47:43

US3432260

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:23:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Sep 2020 17:47:43

US3432260

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 17:47:57

US3432260

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:31

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 17:47:57

US3432260

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 16:55:03

US3432260

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:31

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 16:55:03

US3432260

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 16:55:03

US3432260

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	21 Sep 2020 16:55:03

US3432260

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 16:55:03

US3432260

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '12:17'	(b) (4), (b) (6)	21 Sep 2020 16:55:03

US3432260

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:17'	System	21 Sep 2020 16:55:03

US3432260

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	21 Sep 2020 16:55:03

US3432260

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:31

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	21 Sep 2020 16:55:03

US3432260

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:23:31

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	21 Sep 2020 16:55:03

US3432260

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 21:44:32

US3432260

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 21:44:32

US3432260

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '11:46' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 21:44:55
User entered '12:00'	(b) (4), (b) (6)	21 Sep 2020 21:44:32

US3432260

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:46'	System	21 Sep 2020 21:44:55
User entered '21 Sep 2020 12:00'	System	21 Sep 2020 21:44:32

US3432260

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:23:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Sep 2020'	(b) (4), (b) (6)	21 Sep 2020 21:44:47

US3432260

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:31

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	21 Sep 2020 21:44:47

US3432260

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 21:44:47

US3432260

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '12:00'	(b) (4), (b) (6)	21 Sep 2020 21:44:47

US3432260

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	21 Sep 2020 21:44:47

US3432260

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:31

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	21 Sep 2020 21:44:47

US3432260

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	21 Sep 2020 21:44:47

US3432260

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	21 Sep 2020 21:44:47

US3432260

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 21:44:47

US3432260

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Sep 2020 17:48:09

US3432260

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 17:48:09

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:55:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-21T12:55:33', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '930e06f2-42b9-4eb9-ae7c-3f873af6771b'	System	21 Sep 2020 16:55:51
User entered 'Yes (Y)'	System	21 Sep 2020 16:55:51

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-21T12:55:37', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '930e06f2-42b9-4eb9-ae7c-3f873af6771b' User entered '98.4'	System	21 Sep 2020 16:55:51

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-21T12:55:39', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '930e06f2-42b9-4eb9-ae7c-3f873af6771b'	System	21 Sep 2020 16:55:51
User entered 'No (N)'	System	21 Sep 2020 16:55:51

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-21T12:55:42', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '930e06f2-42b9-4eb9-ae7c-3f873af6771b'	System	21 Sep 2020 16:55:51
User entered '21 Sep 2020 12:55'	System	21 Sep 2020 16:55:51

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:37'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 15:07'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:55:03
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-21T17:21:17', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '8c13f677-f3bf-4bda-89a5-e2cef153f376'	System	21 Sep 2020 21:21:51
User entered 'Yes (Y)'	System	21 Sep 2020 21:21:51

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-21T17:21:22', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '8c13f677-f3bf-4bda-89a5-e2cef153f376'	System	21 Sep 2020 21:21:51
User entered '98.6'	System	21 Sep 2020 21:21:51

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-21T17:21:41', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '8c13f677-f3bf-4bda-89a5-e2cef153f376'	System	21 Sep 2020 21:21:51
User entered 'No (N)'	System	21 Sep 2020 21:21:51

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-21T17:21:49', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '8c13f677-f3bf-4bda-89a5-e2cef153f376'	System	21 Sep 2020 21:21:51
User entered '21 Sep 2020 17:21'	System	21 Sep 2020 21:21:51

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 16:02'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:55:03
User entered 'Day 2'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-22T19:26:57', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'a1f0c7ac-6bed-4dd1-ac9c-47f3d2c0d35e'	System	22 Sep 2020 23:27:11
User entered 'Yes (Y)'	System	22 Sep 2020 23:27:11

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-22T19:27:03', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'a1f0c7ac-6bed-4dd1-ac9c-47f3d2c0d35e' User entered '98.7'	System	22 Sep 2020 23:27:11
	System	22 Sep 2020 23:27:11

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-22T19:27:05', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'a1f0c7ac-6bed-4dd1-ac9c-47f3d2c0d35e'	System	22 Sep 2020 23:27:11
User entered 'No (N)'	System	22 Sep 2020 23:27:11

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-22T19:27:08', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'a1f0c7ac-6bed-4dd1-ac9c-47f3d2c0d35e'	System	22 Sep 2020 23:27:11
User entered '22 Sep 2020 19:27'	System	22 Sep 2020 23:27:11

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:55:03
User entered 'Day 3'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-24T07:16:23', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '780a7cb6-1f4d-4f2e-8cc6-f424937234ba' User entered 'Yes (Y)'	System	24 Sep 2020 11:16:42

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-24T07:16:27', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '780a7cb6-1f4d-4f2e-8cc6-f424937234ba' User entered '98.6'	System	24 Sep 2020 11:16:42

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-24T07:16:31', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '780a7cb6-1f4d-4f2e-8cc6-f424937234ba'	System	24 Sep 2020 11:16:42
User entered 'No (N)'	System	24 Sep 2020 11:16:42

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-24T07:16:33', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '780a7cb6-1f4d-4f2e-8cc6-f424937234ba' User entered '24 Sep 2020 07:16'	System	24 Sep 2020 11:16:42
	System	24 Sep 2020 11:16:42

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:55:03
User entered 'Day 4'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-25T06:21:02', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '7a874df5-071d-4fdc-a52b-0e80bc47f1cc'	System	25 Sep 2020 10:21:25
User entered 'Yes (Y)'	System	25 Sep 2020 10:21:25

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:31

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-25T06:21:06', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '7a874df5-071d-4fdc-a52b-0e80bc47f1cc'	System	25 Sep 2020 10:21:25
User entered '98.9'	System	25 Sep 2020 10:21:25

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-25T06:21:12', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '7a874df5-071d-4fdc-a52b-0e80bc47f1cc'	System	25 Sep 2020 10:21:25
User entered 'Yes (Y)'	System	25 Sep 2020 10:21:25

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'participant contacted and ibuprofen added to conmeds' (Site from System).	(b) (4), (b) (6)	30 Sep 2020 16:54:26
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-25T06:21:19', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '7a874df5-071d-4fdc-a52b-0e80bc47f1cc'	Phoebe Cunningham (b) (4)	28 Sep 2020 21:27:49
User entered '1'	System	25 Sep 2020 10:21:25
	System	25 Sep 2020 10:21:25
	System	25 Sep 2020 10:21:25

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:31

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-25T06:21:19', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '7a874df5-071d-4fdc-a52b-0e80bc47f1cc'	System	25 Sep 2020 10:21:25
User entered '0'	System	25 Sep 2020 10:21:25

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-25T06:21:22', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '7a874df5-071d-4fdc-a52b-0e80bc47f1cc'	System	25 Sep 2020 10:21:25
User entered '25 Sep 2020 06:21'	System	25 Sep 2020 10:21:25

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:55:03
User entered 'Day 5'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-25T12:07:35', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'eefadf9c-84e7-4252-9af5-904c61e869bc' User entered 'Yes (Y)'	System	25 Sep 2020 16:08:02
	System	25 Sep 2020 16:08:02

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-25T12:07:40', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'eefadf9c-84e7-4252-9af5-904c61e869bc' User entered '97.3'	System	25 Sep 2020 16:08:02

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-25T12:07:57', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'eefadf9c-84e7-4252-9af5-904c61e869bc'	System	25 Sep 2020 16:08:02
User entered 'No (N)'	System	25 Sep 2020 16:08:02

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-25T12:07:59', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'eefadf9c-84e7-4252-9af5-904c61e869bc' User entered '25 Sep 2020 12:07'	System	25 Sep 2020 16:08:02
	System	25 Sep 2020 16:08:02

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:55:03
User entered 'Day 6'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-26T20:13:51', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'e263fc50-9d11-46a1-a49d-ca982d256145'	System	27 Sep 2020 00:14:08
User entered 'Yes (Y)'	System	27 Sep 2020 00:14:08

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-26T20:13:55', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'e263fc50-9d11-46a1-a49d-ca982d256145'	System	27 Sep 2020 00:14:08
User entered '99.8'	System	27 Sep 2020 00:14:08

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-26T20:14:00', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'e263fc50-9d11-46a1-a49d-ca982d256145'	System	27 Sep 2020 00:14:08
User entered 'No (N)'	System	27 Sep 2020 00:14:08

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-26T20:14:02', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'e263fc50-9d11-46a1-a49d-ca982d256145'	System	27 Sep 2020 00:14:08
User entered '26 Sep 2020 20:14'	System	27 Sep 2020 00:14:08

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:55:03
User entered 'Day 7'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-28T07:22:46', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '79aae3ba-860e-4272-918c-f3386074e9ac'	System	28 Sep 2020 11:23:04
User entered 'Yes (Y)'	System	28 Sep 2020 11:23:04

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-28T07:22:52', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '79aae3ba-860e-4272-918c-f3386074e9ac'	System	28 Sep 2020 11:23:04
User entered '99.0'	System	28 Sep 2020 11:23:04

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-28T07:22:55', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '79aae3ba-860e-4272-918c-f3386074e9ac'	System	28 Sep 2020 11:23:04
User entered 'No (N)'	System	28 Sep 2020 11:23:04

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-28T07:22:57', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '79aae3ba-860e-4272-918c-f3386074e9ac'	System	28 Sep 2020 11:23:04
User entered '28 Sep 2020 07:22'	System	28 Sep 2020 11:23:04

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:55:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-21T12:55:46', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'bc35d2fe-27c0-44aa-91df-57fa9e64290e'	System	21 Sep 2020 16:55:58
User entered 'None (1)'	System	21 Sep 2020 16:55:58

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-21T12:55:48', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'bc35d2fe-27c0-44aa-91df-57fa9e64290e'	System	21 Sep 2020 16:55:58
User entered 'No (N)'	System	21 Sep 2020 16:55:58

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-21T12:55:50', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'bc35d2fe-27c0-44aa-91df-57fa9e64290e'	System	21 Sep 2020 16:55:58
User entered 'No (N)'	System	21 Sep 2020 16:55:58

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-21T12:55:53', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'bc35d2fe-27c0-44aa-91df-57fa9e64290e'	System	21 Sep 2020 16:55:58
User entered 'None (1)'	System	21 Sep 2020 16:55:58

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-21T12:55:55', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'bc35d2fe-27c0-44aa-91df-57fa9e64290e'	System	21 Sep 2020 16:55:58
User entered '21 Sep 2020 12:55'	System	21 Sep 2020 16:55:58

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:37'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 15:07'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:55:03
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-21T17:21:55', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '2a5d1228-6447-4b4e-b0ca-c577c73ec369'	System	21 Sep 2020 21:22:09
User entered 'Does not interfere with activity (2)'	System	21 Sep 2020 21:22:09

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-21T17:21:57', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '2a5d1228-6447-4b4e-b0ca-c577c73ec369'	System	21 Sep 2020 21:22:09
User entered 'No (N)'	System	21 Sep 2020 21:22:09

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-21T17:22:00', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '2a5d1228-6447-4b4e-b0ca-c577c73ec369'	System	21 Sep 2020 21:22:09
User entered 'No (N)'	System	21 Sep 2020 21:22:09

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-21T17:22:03', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '2a5d1228-6447-4b4e-b0ca-c577c73ec369'	System	21 Sep 2020 21:22:09
User entered 'None (1)'	System	21 Sep 2020 21:22:09

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-21T17:22:05', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '2a5d1228-6447-4b4e-b0ca-c577c73ec369'	System	21 Sep 2020 21:22:09
User entered '21 Sep 2020 17:22'	System	21 Sep 2020 21:22:09

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 16:02'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:55:03
User entered 'Day 2'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:31

[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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-22T19:27:16', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'fe39977c-f6bb-4fda-88d2-09751a4bea31'	System	22 Sep 2020 23:27:31
User entered 'None (1)'	System	22 Sep 2020 23:27:31

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-22T19:27:18', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'fe39977c-f6bb-4fda-88d2-09751a4bea31'	System	22 Sep 2020 23:27:31
User entered 'No (N)'	System	22 Sep 2020 23:27:31

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-22T19:27:21', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'fe39977c-f6bb-4fda-88d2-09751a4bea31'	System	22 Sep 2020 23:27:31
User entered 'No (N)'	System	22 Sep 2020 23:27:31

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-22T19:27:23', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'fe39977c-f6bb-4fda-88d2-09751a4bea31'	System	22 Sep 2020 23:27:31
User entered 'None (1)'	System	22 Sep 2020 23:27:31

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-22T19:27:26', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'fe39977c-f6bb-4fda-88d2-09751a4bea31'	System	22 Sep 2020 23:27:31
User entered '22 Sep 2020 19:27'	System	22 Sep 2020 23:27:31

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:55:03
User entered 'Day 3'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-24T07:16:37', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'b8b6063f-ebff-4971-9d43-39052ef35f3f'	System	24 Sep 2020 11:16:48
User entered 'None (1)'	System	24 Sep 2020 11:16:48

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-24T07:16:40', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'b8b6063f-ebff-4971-9d43-39052ef35f3f'	System	24 Sep 2020 11:16:48
User entered 'No (N)'	System	24 Sep 2020 11:16:48

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-24T07:16:41', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'b8b6063f-ebff-4971-9d43-39052ef35f3f'	System	24 Sep 2020 11:16:48
User entered 'No (N)'	System	24 Sep 2020 11:16:48

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-24T07:16:43', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'b8b6063f-ebff-4971-9d43-39052ef35f3f'	System	24 Sep 2020 11:16:48
User entered 'None (1)'	System	24 Sep 2020 11:16:48

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-24T07:16:46', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'b8b6063f-ebff-4971-9d43-39052ef35f3f'	System	24 Sep 2020 11:16:48
User entered '24 Sep 2020 07:16'	System	24 Sep 2020 11:16:48

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:55:03
User entered 'Day 4'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-25T06:21:25', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'c04ea8f2-6812-4bb3-8432-624decf38e1e'	System	25 Sep 2020 10:21:39
User entered 'None (1)'	System	25 Sep 2020 10:21:39

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-25T06:21:28', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'c04ea8f2-6812-4bb3-8432-624decf38e1e'	System	25 Sep 2020 10:21:39
User entered 'No (N)'	System	25 Sep 2020 10:21:39

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-25T06:21:31', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'c04ea8f2-6812-4bb3-8432-624decf38e1e'	System	25 Sep 2020 10:21:39
User entered 'No (N)'	System	25 Sep 2020 10:21:39

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-25T06:21:34', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'c04ea8f2-6812-4bb3-8432-624decf38e1e'	System	25 Sep 2020 10:21:39
User entered 'None (1)'	System	25 Sep 2020 10:21:39

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-25T06:21:37', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'c04ea8f2-6812-4bb3-8432-624decf38e1e'	System	25 Sep 2020 10:21:39
User entered '25 Sep 2020 06:21'	System	25 Sep 2020 10:21:39

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:55:03
User entered 'Day 5'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-25T12:08:02', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '275eced8-ce30-48b4-87c7-0b10d5aeab2b' User entered 'None (1)'	System	25 Sep 2020 16:08:15
	System	25 Sep 2020 16:08:15

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-25T12:08:05', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '275eced8-ce30-48b4-87c7-0b10d5aeab2b'	System	25 Sep 2020 16:08:15
User entered 'No (N)'	System	25 Sep 2020 16:08:15

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-25T12:08:08', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '275eced8-ce30-48b4-87c7-0b10d5aeab2b' User entered 'No (N)'	System	25 Sep 2020 16:08:15

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-25T12:08:10', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '275eced8-ce30-48b4-87c7-0b10d5aeab2b' User entered 'None (1)'	System	25 Sep 2020 16:08:15
	System	25 Sep 2020 16:08:15

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-25T12:08:12', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '275eced8-ce30-48b4-87c7-0b10d5aeab2b' User entered '25 Sep 2020 12:08'	System	25 Sep 2020 16:08:15
	System	25 Sep 2020 16:08:15

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:55:03
User entered 'Day 6'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-26T20:14:05', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '0347f623-44c1-4624-b7dd-cfaafc6225f3'	System	27 Sep 2020 00:14:15
User entered 'None (1)'	System	27 Sep 2020 00:14:15

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-26T20:14:08', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '0347f623-44c1-4624-b7dd-cfaafc6225f3'	System	27 Sep 2020 00:14:15
User entered 'No (N)'	System	27 Sep 2020 00:14:15

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-26T20:14:09', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '0347f623-44c1-4624-b7dd-cfaafc6225f3'	System	27 Sep 2020 00:14:15
User entered 'No (N)'	System	27 Sep 2020 00:14:15

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-26T20:14:11', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '0347f623-44c1-4624-b7dd-cfaafc6225f3'	System	27 Sep 2020 00:14:15
User entered 'None (1)'	System	27 Sep 2020 00:14:15

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-26T20:14:13', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '0347f623-44c1-4624-b7dd-cfaafc6225f3'	System	27 Sep 2020 00:14:15
User entered '26 Sep 2020 20:14'	System	27 Sep 2020 00:14:15

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:55:03
User entered 'Day 7'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-28T07:23:00', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '66f5e558-9b9f-4a38-a23b-9a2d266a0c44'	System	28 Sep 2020 11:23:12
User entered 'None (1)'	System	28 Sep 2020 11:23:12

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-28T07:23:02', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '66f5e558-9b9f-4a38-a23b-9a2d266a0c44'	System	28 Sep 2020 11:23:12
User entered 'No (N)'	System	28 Sep 2020 11:23:12

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-28T07:23:04', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '66f5e558-9b9f-4a38-a23b-9a2d266a0c44'	System	28 Sep 2020 11:23:12
User entered 'No (N)'	System	28 Sep 2020 11:23:12

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-28T07:23:05', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '66f5e558-9b9f-4a38-a23b-9a2d266a0c44'	System	28 Sep 2020 11:23:12
User entered 'None (1)'	System	28 Sep 2020 11:23:12

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-28T07:23:08', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '66f5e558-9b9f-4a38-a23b-9a2d266a0c44'	System	28 Sep 2020 11:23:12
User entered '28 Sep 2020 07:23'	System	28 Sep 2020 11:23:12

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:55:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-21T12:55:58', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '5a1c8ab0-5de5-4229-9023-a7f3bab4e9b6'	System	21 Sep 2020 16:56:12
User entered 'None (0)'	System	21 Sep 2020 16:56:12

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-21T12:56:00', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '5a1c8ab0-5de5-4229-9023-a7f3bab4e9b6'	System	21 Sep 2020 16:56:12
User entered 'None (0)'	System	21 Sep 2020 16:56:12

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-21T12:56:02', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '5a1c8ab0-5de5-4229-9023-a7f3bab4e9b6'	System	21 Sep 2020 16:56:12
User entered 'None (0)'	System	21 Sep 2020 16:56:12

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-21T12:56:03', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '5a1c8ab0-5de5-4229-9023-a7f3bab4e9b6'	System	21 Sep 2020 16:56:12
User entered 'None (0)'	System	21 Sep 2020 16:56:12

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-21T12:56:05', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '5a1c8ab0-5de5-4229-9023-a7f3bab4e9b6'	System	21 Sep 2020 16:56:12
User entered 'None (0)'	System	21 Sep 2020 16:56:12

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-21T12:56:07', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '5a1c8ab0-5de5-4229-9023-a7f3bab4e9b6'	System	21 Sep 2020 16:56:12
User entered 'None (0)'	System	21 Sep 2020 16:56:12

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-21T12:56:09', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '5a1c8ab0-5de5-4229-9023-a7f3bab4e9b6'	System	21 Sep 2020 16:56:12
User entered 'No (N)'	System	21 Sep 2020 16:56:12

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-21T12:56:11', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '5a1c8ab0-5de5-4229-9023-a7f3bab4e9b6'	System	21 Sep 2020 16:56:12
User entered '21 Sep 2020 12:56'	System	21 Sep 2020 16:56:12

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:37'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 15:07'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:55:03
User entered 'Day 1, after vaccination (at home)'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-21T17:22:09', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '90c69c4b-df2a-41a9-93fb-7be83523983e'	System	21 Sep 2020 21:22:27
User entered 'None (0)'	System	21 Sep 2020 21:22:27

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-21T17:22:11', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '90c69c4b-df2a-41a9-93fb-7be83523983e'	System	21 Sep 2020 21:22:27
User entered 'None (0)'	System	21 Sep 2020 21:22:27

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-21T17:22:14', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '90c69c4b-df2a-41a9-93fb-7be83523983e'	System	21 Sep 2020 21:22:27
User entered 'None (0)'	System	21 Sep 2020 21:22:27

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-21T17:22:16', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '90c69c4b-df2a-41a9-93fb-7be83523983e' User entered 'None (0)'	System	21 Sep 2020 21:22:27
	System	21 Sep 2020 21:22:27

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-21T17:22:18', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '90c69c4b-df2a-41a9-93fb-7be83523983e' User entered 'None (0)'	System	21 Sep 2020 21:22:27
	System	21 Sep 2020 21:22:27

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-21T17:22:20', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '90c69c4b-df2a-41a9-93fb-7be83523983e'	System	21 Sep 2020 21:22:27
User entered 'None (0)'	System	21 Sep 2020 21:22:27

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-21T17:22:23', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '90c69c4b-df2a-41a9-93fb-7be83523983e' User entered 'No (N)'	System	21 Sep 2020 21:22:27

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-21T17:22:25', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '90c69c4b-df2a-41a9-93fb-7be83523983e'	System	21 Sep 2020 21:22:27
User entered '21 Sep 2020 17:22'	System	21 Sep 2020 21:22:27

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 16:02'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:55:03
User entered 'Day 2'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-22T19:27:31', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '651f4a39-0263-4746-b797-b7e91ae3a8cf'	System	22 Sep 2020 23:27:56
User entered 'None (0)'	System	22 Sep 2020 23:27:56

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-22T19:27:36', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '651f4a39-0263-4746-b797-b7e91ae3a8cf'	System	22 Sep 2020 23:27:56
User entered 'No interference with activity (1)'	System	22 Sep 2020 23:27:56

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-22T19:27:41', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '651f4a39-0263-4746-b797-b7e91ae3a8cf'	System	22 Sep 2020 23:27:56
User entered 'No interference with activity (1)'	System	22 Sep 2020 23:27:56

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-22T19:27:44', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '651f4a39-0263-4746-b797-b7e91ae3a8cf'	System	22 Sep 2020 23:27:56
User entered 'No interference with activity (1)'	System	22 Sep 2020 23:27:56

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-22T19:27:47', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '651f4a39-0263-4746-b797-b7e91ae3a8cf'	System	22 Sep 2020 23:27:56
User entered 'None (0)'	System	22 Sep 2020 23:27:56

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-22T19:27:49', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '651f4a39-0263-4746-b797-b7e91ae3a8cf'	System	22 Sep 2020 23:27:56
User entered 'No interference with activity (1)'	System	22 Sep 2020 23:27:56

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-22T19:27:52', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '651f4a39-0263-4746-b797-b7e91ae3a8cf'	System	22 Sep 2020 23:27:56
User entered 'No (N)'	System	22 Sep 2020 23:27:56

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-22T19:27:54', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '651f4a39-0263-4746-b797-b7e91ae3a8cf'	System	22 Sep 2020 23:27:56
User entered '22 Sep 2020 19:27'	System	22 Sep 2020 23:27:56

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:55:03
User entered 'Day 3'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-24T07:16:50', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '18172751-25db-459d-bd14-5a6fe9d82899'	System	24 Sep 2020 11:17:10
User entered 'None (0)'	System	24 Sep 2020 11:17:10

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-24T07:16:53', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '18172751-25db-459d-bd14-5a6fe9d82899'	System	24 Sep 2020 11:17:10
User entered 'No interference with activity (1)'	System	24 Sep 2020 11:17:10

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-24T07:16:56', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '18172751-25db-459d-bd14-5a6fe9d82899'	System	24 Sep 2020 11:17:10
User entered 'No interference with activity (1)'	System	24 Sep 2020 11:17:10

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-24T07:16:59', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '18172751-25db-459d-bd14-5a6fe9d82899'	System	24 Sep 2020 11:17:10
User entered 'No interference with activity (1)'	System	24 Sep 2020 11:17:10

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-24T07:17:01', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '18172751-25db-459d-bd14-5a6fe9d82899'	System	24 Sep 2020 11:17:10
User entered 'None (0)'	System	24 Sep 2020 11:17:10

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-24T07:17:03', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '18172751-25db-459d-bd14-5a6fe9d82899'	System	24 Sep 2020 11:17:10
User entered 'None (0)'	System	24 Sep 2020 11:17:10

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-24T07:17:06', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '18172751-25db-459d-bd14-5a6fe9d82899'	System	24 Sep 2020 11:17:10
User entered 'No (N)'	System	24 Sep 2020 11:17:10

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-24T07:17:08', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '18172751-25db-459d-bd14-5a6fe9d82899'	System	24 Sep 2020 11:17:10
User entered '24 Sep 2020 07:17'	System	24 Sep 2020 11:17:10

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:55:03
User entered 'Day 4'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-25T06:21:41', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'b5d4289e-7737-4b02-a5f6-fbc9036adbef'	System	25 Sep 2020 10:22:11
User entered 'None (0)'	System	25 Sep 2020 10:22:11

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-25T06:21:45', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'b5d4289e-7737-4b02-a5f6-fbc9036adbef'	System	25 Sep 2020 10:22:11
User entered 'None (0)'	System	25 Sep 2020 10:22:11

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-25T06:21:53', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'b5d4289e-7737-4b02-a5f6-fbc9036adbef'	System	25 Sep 2020 10:22:11
User entered 'No interference with activity (1)'	System	25 Sep 2020 10:22:11

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-25T06:21:56', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'b5d4289e-7737-4b02-a5f6-fbc9036adbf'	System	25 Sep 2020 10:22:11
User entered 'Some interference with activity (2)'	System	25 Sep 2020 10:22:11

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-25T06:21:58', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'b5d4289e-7737-4b02-a5f6-fbc9036adbf'	System	25 Sep 2020 10:22:11
User entered 'None (0)'	System	25 Sep 2020 10:22:11

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-25T06:22:00', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'b5d4289e-7737-4b02-a5f6-fbc9036adbf'	System	25 Sep 2020 10:22:11
User entered 'None (0)'	System	25 Sep 2020 10:22:11

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-25T06:22:07', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'b5d4289e-7737-4b02-a5f6-fbc9036adbf'	System	25 Sep 2020 10:22:11
User entered 'No (N)'	System	25 Sep 2020 10:22:11

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-25T06:22:09', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'b5d4289e-7737-4b02-a5f6-fbc9036adbef' User entered '25 Sep 2020 06:22'	System	25 Sep 2020 10:22:11
	System	25 Sep 2020 10:22:11

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 12:00'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 11:59'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:55:03
User entered 'Day 5'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-25T12:13:47', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '11319eab-2a1f-4847-9478-88228fc24e5d'	System	25 Sep 2020 16:14:12
User entered 'None (0)'	System	25 Sep 2020 16:14:12

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-25T12:13:52', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '11319eab-2a1f-4847-9478-88228fc24e5d' User entered 'None (0)'	System	25 Sep 2020 16:14:12
	System	25 Sep 2020 16:14:12

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-25T12:13:56', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '11319eab-2a1f-4847-9478-88228fc24e5d'	System	25 Sep 2020 16:14:12
User entered 'No interference with activity (1)'	System	25 Sep 2020 16:14:12

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-25T12:13:58', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '11319eab-2a1f-4847-9478-88228fc24e5d'	System	25 Sep 2020 16:14:12
User entered 'Some interference with activity (2)'	System	25 Sep 2020 16:14:12

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-25T12:14:00', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '11319eab-2a1f-4847-9478-88228fc24e5d'	System	25 Sep 2020 16:14:12
User entered 'None (0)'	System	25 Sep 2020 16:14:12

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-25T12:14:03', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '11319eab-2a1f-4847-9478-88228fc24e5d'	System	25 Sep 2020 16:14:12
User entered 'None (0)'	System	25 Sep 2020 16:14:12

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-25T12:14:06', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '11319eab-2a1f-4847-9478-88228fc24e5d'	System	25 Sep 2020 16:14:12
User entered 'No (N)'	System	25 Sep 2020 16:14:12

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-25T12:14:08', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '11319eab-2a1f-4847-9478-88228fc24e5d'	System	25 Sep 2020 16:14:12
User entered '25 Sep 2020 12:14'	System	25 Sep 2020 16:14:12

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Sep 2020 12:00'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 11:59'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:55:03
User entered 'Day 6'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-26T20:14:17', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'b8fb10b8-e89c-4bb6-ba8a-d1fbe6255481'	System	27 Sep 2020 00:14:37
User entered 'None (0)'	System	27 Sep 2020 00:14:37

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-26T20:14:20', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'b8fb10b8-e89c-4bb6-ba8a-d1fbe6255481'	System	27 Sep 2020 00:14:37
User entered 'None (0)'	System	27 Sep 2020 00:14:37

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-26T20:14:23', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'b8fb10b8-e89c-4bb6-ba8a-d1fbe6255481'	System	27 Sep 2020 00:14:37
User entered 'No interference with activity (1)'	System	27 Sep 2020 00:14:37

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-26T20:14:26', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'b8fb10b8-e89c-4bb6-ba8a-d1fbe6255481'	System	27 Sep 2020 00:14:37
User entered 'No interference with activity (1)'	System	27 Sep 2020 00:14:37

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-26T20:14:28', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'b8fb10b8-e89c-4bb6-ba8a-d1fbe6255481'	System	27 Sep 2020 00:14:37
User entered 'None (0)'	System	27 Sep 2020 00:14:37

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-26T20:14:30', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'b8fb10b8-e89c-4bb6-ba8a-d1fbe6255481'	System	27 Sep 2020 00:14:37
User entered 'None (0)'	System	27 Sep 2020 00:14:37

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-26T20:14:33', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'b8fb10b8-e89c-4bb6-ba8a-d1fbe6255481'	System	27 Sep 2020 00:14:37
User entered 'No (N)'	System	27 Sep 2020 00:14:37

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-26T20:14:35', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'b8fb10b8-e89c-4bb6-ba8a-d1fbe6255481'	System	27 Sep 2020 00:14:37
User entered '26 Sep 2020 20:14'	System	27 Sep 2020 00:14:37

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Sep 2020 12:00'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 11:59'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	21 Sep 2020 16:55:03
User entered 'Day 7'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:31

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-28T07:23:11', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '6da38941-d713-4979-9aa8-44ac4484b976'	System	28 Sep 2020 11:23:35
User entered 'None (0)'	System	28 Sep 2020 11:23:35

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:31

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-28T07:23:15', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '6da38941-d713-4979-9aa8-44ac4484b976'	System	28 Sep 2020 11:23:35
User entered 'None (0)'	System	28 Sep 2020 11:23:35

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-28T07:23:17', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '6da38941-d713-4979-9aa8-44ac4484b976'	System	28 Sep 2020 11:23:35
User entered 'None (0)'	System	28 Sep 2020 11:23:35

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-28T07:23:20', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '6da38941-d713-4979-9aa8-44ac4484b976'	System	28 Sep 2020 11:23:35
User entered 'No interference with activity (1)'	System	28 Sep 2020 11:23:35

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-28T07:23:22', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '6da38941-d713-4979-9aa8-44ac4484b976'	System	28 Sep 2020 11:23:35
User entered 'None (0)'	System	28 Sep 2020 11:23:35

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:31

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-28T07:23:24', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '6da38941-d713-4979-9aa8-44ac4484b976'	System	28 Sep 2020 11:23:35
User entered 'No interference with activity (1)'	System	28 Sep 2020 11:23:35

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-28T07:23:27', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '6da38941-d713-4979-9aa8-44ac4484b976'	System	28 Sep 2020 11:23:35
User entered 'No (N)'	System	28 Sep 2020 11:23:35

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-28T07:23:28', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '6da38941-d713-4979-9aa8-44ac4484b976'	System	28 Sep 2020 11:23:35
User entered '28 Sep 2020 07:23'	System	28 Sep 2020 11:23:35

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Sep 2020 12:00'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 11:59'	System	21 Sep 2020 16:55:03

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Sep 2020 00:14:37
User entered 'Day 8'	System	27 Sep 2020 00:14:37

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:23:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-29T09:48:45', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'd64a1aea-aff5-467c-af6d-da98bf10522f'	System	29 Sep 2020 13:48:50
User entered 'No interference with activity (1)'	System	29 Sep 2020 13:48:50

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-29T09:48:47', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'd64a1aea-aff5-467c-af6d-da98bf10522f' User entered '29 Sep 2020 09:48'	System	29 Sep 2020 13:48:50
	System	29 Sep 2020 13:48:50

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	27 Sep 2020 00:14:37

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	27 Sep 2020 00:14:37

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Sep 2020 11:23:35
User entered 'Day 9'	System	28 Sep 2020 11:23:35

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 11:23:35

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 11:23:35

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 13:48:50
User entered 'Day 10'	System	29 Sep 2020 13:48:50

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 09:23:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-30T13:36:12', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'ff96ec4b-0565-45a6-9cf2-5fc728d1c749'	System	30 Sep 2020 17:36:18
User entered 'No interference with activity (1)'	System	30 Sep 2020 17:36:18

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-30T13:36:14', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'ff96ec4b-0565-45a6-9cf2-5fc728d1c749'	System	30 Sep 2020 17:36:18
User entered '30 Sep 2020 13:36'	System	30 Sep 2020 17:36:18

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 13:48:50

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(10)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 13:48:50

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 17:36:18
User entered 'Day 11'	System	30 Sep 2020 17:36:18

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 09:23:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-10-01T16:38:40', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '130f15b5-aba9-4964-8b02-9501fa31cbb8'	System	01 Oct 2020 20:38:45
User entered 'No interference with activity (1)'	System	01 Oct 2020 20:38:45

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-10-01T16:38:42', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '130f15b5-aba9-4964-8b02-9501fa31cbb8'	System	01 Oct 2020 20:38:45
User entered '01 Oct 2020 16:38'	System	01 Oct 2020 20:38:45

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 17:36:18

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(11)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 17:36:18

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 17:36:18
User entered 'Day 12'	System	30 Sep 2020 17:36:18

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 09:23:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-10-02T20:00:26', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'f80f596c-6464-4fa0-9a10-8f8b34679e7f'	System	03 Oct 2020 00:00:43
User entered 'No interference with activity (1)'	System	03 Oct 2020 00:00:43

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-10-02T20:00:29', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'f80f596c-6464-4fa0-9a10-8f8b34679e7f'	System	03 Oct 2020 00:00:43
User entered '02 Oct 2020 20:00'	System	03 Oct 2020 00:00:43

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 17:36:18

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(12)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 17:36:18

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 20:38:45
User entered 'Day 13'	System	01 Oct 2020 20:38:45

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 09:23:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-10-04T07:57:51', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '7e23ae4e-083a-4bec-92b8-6eec87ff87f2'	System	04 Oct 2020 11:57:57
User entered 'No interference with activity (1)'	System	04 Oct 2020 11:57:57

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-10-04T07:57:53', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '7e23ae4e-083a-4bec-92b8-6eec87ff87f2'	System	04 Oct 2020 11:57:57
User entered '04 Oct 2020 07:57'	System	04 Oct 2020 11:57:57

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 20:38:45

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(13)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 20:38:45

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Oct 2020 00:00:43
User entered 'Day 14'	System	03 Oct 2020 00:00:43

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 09:23:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-10-05T06:30:16', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '937c9f6a-1196-46d2-8cd8-495eff4e36eb'	System	05 Oct 2020 10:30:23
User entered 'No interference with activity (1)'	System	05 Oct 2020 10:30:23

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-10-05T06:30:19', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '937c9f6a-1196-46d2-8cd8-495eff4e36eb' User entered '05 Oct 2020 06:30'	System	05 Oct 2020 10:30:23
	System	05 Oct 2020 10:30:23

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	03 Oct 2020 00:00:43

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(14)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	03 Oct 2020 00:00:43

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Oct 2020 11:57:57
User entered 'Day 15'	System	04 Oct 2020 11:57:57

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 26 Nov 2020 09:23:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-10-05T12:00:14', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'b756678c-14c9-4054-89f8-a6d8ff321bd3'	System	05 Oct 2020 16:00:21
User entered 'No interference with activity (1)'	System	05 Oct 2020 16:00:21

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-10-05T12:00:16', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'b756678c-14c9-4054-89f8-a6d8ff321bd3'	System	05 Oct 2020 16:00:21
User entered '05 Oct 2020 12:00'	System	05 Oct 2020 16:00:21

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 11:57:57

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(15)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 11:57:57

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Oct 2020 10:30:23
User entered 'Day 16'	System	05 Oct 2020 10:30:23

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 10:30:23

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(16)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 10:30:23

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Oct 2020 16:00:21
User entered 'Day 17'	System	05 Oct 2020 16:00:21

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 26 Nov 2020 09:23:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-10-08T09:35:48', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '9e51e367-a25a-4007-8c40-a79a3ae1cf4b'	System	08 Oct 2020 13:35:52
User entered 'No interference with activity (1)'	System	08 Oct 2020 13:35:52

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-10-08T09:35:50', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '9e51e367-a25a-4007-8c40-a79a3ae1cf4b'	System	08 Oct 2020 13:35:52
User entered '08 Oct 2020 09:35'	System	08 Oct 2020 13:35:52

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 16:00:21

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(17)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 16:00:21

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 13:35:52
User entered 'Day 18'	System	08 Oct 2020 13:35:52

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 26 Nov 2020 09:23:31

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-10-09T11:22:12', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '1fffcc45-8722-4de9-be6c-600c5ef48a18'	System	09 Oct 2020 15:22:17
User entered 'None (0)'	System	09 Oct 2020 15:22:17

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-10-09T11:22:15', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '1fffcc45-8722-4de9-be6c-600c5ef48a18'	System	09 Oct 2020 15:22:17
User entered '09 Oct 2020 11:22'	System	09 Oct 2020 15:22:17

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	08 Oct 2020 13:35:52

US3432260

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(18)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 13:35:52

US3432260

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	28 Sep 2020 11:23:35
User entered 'Day 8'	System	28 Sep 2020 11:23:35

US3432260

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 26 Nov 2020 09:23:31

Select one response below to indicate the intensity of **CHILLS** you are experiencing

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-29T09:48:57', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '75bdc98c-ca1c-4ade-a245-db893b6fddb0'	System	29 Sep 2020 13:49:04
User entered 'None (0)'	System	29 Sep 2020 13:49:04

US3432260

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	28 Sep 2020 11:23:35

US3432260

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 11:23:35

US3432260

Folder: Diary Dose 2 (1)

Form: Chills_Day(8)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-29T09:48:59', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '75bdc98c-ca1c-4ade-a245-db893b6fddb0'	System	29 Sep 2020 13:49:04
User entered '29 Sep 2020 09:48'	System	29 Sep 2020 13:49:04

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	27 Sep 2020 00:14:37
User entered 'Day 8'	System	27 Sep 2020 00:14:37

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-29T09:48:52', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '70fd076d-b3c6-4986-9ad8-56b0e8449b82'	System	29 Sep 2020 13:48:58
User entered 'No (N)'	System	29 Sep 2020 13:48:58

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-29T09:48:54', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '70fd076d-b3c6-4986-9ad8-56b0e8449b82'	System	29 Sep 2020 13:48:58
User entered '29 Sep 2020 09:48'	System	29 Sep 2020 13:48:58

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '28 Sep 2020 12:00'	System	27 Sep 2020 00:14:37

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '29 Sep 2020 11:59'	System	27 Sep 2020 00:14:37

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	29 Sep 2020 13:48:50
User entered 'Day 10'	System	29 Sep 2020 13:48:50

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-30T13:36:18', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '9ad43510-76f4-4f22-98fc-f535a9b5d561'	System	30 Sep 2020 17:36:24
User entered 'Yes (Y)'	System	30 Sep 2020 17:36:24

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-09-30T13:36:21', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '9ad43510-76f4-4f22-98fc-f535a9b5d561'	System	30 Sep 2020 17:36:24
User entered '30 Sep 2020 13:36'	System	30 Sep 2020 17:36:24

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 13:48:50

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 13:48:50

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 17:36:18
User entered 'Day 11'	System	30 Sep 2020 17:36:18

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-10-01T16:38:47', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '0d73aa07-44be-41f4-9ba0-72c2891f8f63'	System	01 Oct 2020 20:38:52
User entered 'No (N)'	System	01 Oct 2020 20:38:52

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-10-01T16:38:48', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '0d73aa07-44be-41f4-9ba0-72c2891f8f63'	System	01 Oct 2020 20:38:52
User entered '01 Oct 2020 16:38'	System	01 Oct 2020 20:38:52

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '01 Oct 2020 12:00'	System	30 Sep 2020 17:36:18

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(11)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 11:59'	System	30 Sep 2020 17:36:18

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	30 Sep 2020 17:36:18
User entered 'Day 12'	System	30 Sep 2020 17:36:18

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-10-02T20:00:33', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'adfd1701-a609-4dc5-b4cc-1f9173c96102'	System	03 Oct 2020 00:00:48
User entered 'No (N)'	System	03 Oct 2020 00:00:48

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-10-02T20:00:35', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'adfd1701-a609-4dc5-b4cc-1f9173c96102'	System	03 Oct 2020 00:00:48
User entered '02 Oct 2020 20:00'	System	03 Oct 2020 00:00:48

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '02 Oct 2020 12:00'	System	30 Sep 2020 17:36:18

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(12)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 11:59'	System	30 Sep 2020 17:36:18

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	01 Oct 2020 20:38:45
User entered 'Day 13'	System	01 Oct 2020 20:38:45

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-10-04T07:57:56', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '0ae89ba3-4638-493a-a04a-5fe165ae2214'	System	04 Oct 2020 11:58:03
User entered 'No (N)'	System	04 Oct 2020 11:58:03

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-10-04T07:57:58', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '0ae89ba3-4638-493a-a04a-5fe165ae2214'	System	04 Oct 2020 11:58:03
User entered '04 Oct 2020 07:57'	System	04 Oct 2020 11:58:03

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '03 Oct 2020 12:00'	System	01 Oct 2020 20:38:45

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(13)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 11:59'	System	01 Oct 2020 20:38:45

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	03 Oct 2020 00:00:43
User entered 'Day 14'	System	03 Oct 2020 00:00:43

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-10-05T06:30:25', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '5143a7f1-b57f-4ba2-89f0-0e66ee71309c'	System	05 Oct 2020 10:30:30
User entered 'No (N)'	System	05 Oct 2020 10:30:30

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-10-05T06:30:28', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '5143a7f1-b57f-4ba2-89f0-0e66ee71309c' User entered '05 Oct 2020 06:30'	System	05 Oct 2020 10:30:30
	System	05 Oct 2020 10:30:30

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '04 Oct 2020 12:00'	System	03 Oct 2020 00:00:43

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(14)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 11:59'	System	03 Oct 2020 00:00:43

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	04 Oct 2020 11:57:57
User entered 'Day 15'	System	04 Oct 2020 11:57:57

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-10-05T12:00:20', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'f4a18862-caa5-4aa0-9380-afa16860d45e'	System	05 Oct 2020 16:00:27
User entered 'No (N)'	System	05 Oct 2020 16:00:27

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-10-05T12:00:22', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'f4a18862-caa5-4aa0-9380-afa16860d45e' User entered '05 Oct 2020 12:00'	System	05 Oct 2020 16:00:27
	System	05 Oct 2020 16:00:27

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 11:57:57

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(15)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 11:57:57

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Oct 2020 10:30:23
User entered 'Day 16'	System	05 Oct 2020 10:30:23

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 10:30:23

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(16)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 10:30:23

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	05 Oct 2020 16:00:21
User entered 'Day 17'	System	05 Oct 2020 16:00:21

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-10-08T09:35:54', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '2188d2c3-4b70-4ed6-bb87-fc974be6eea4'	System	08 Oct 2020 13:36:08
User entered 'No (N)'	System	08 Oct 2020 13:36:08

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-10-08T09:36:04', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '2188d2c3-4b70-4ed6-bb87-fc974be6eea4'	System	08 Oct 2020 13:36:08
User entered '08 Oct 2020 09:36'	System	08 Oct 2020 13:36:08

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '07 Oct 2020 12:00'	System	05 Oct 2020 16:00:21

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(17)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 11:59'	System	05 Oct 2020 16:00:21

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	08 Oct 2020 13:35:52
User entered 'Day 18'	System	08 Oct 2020 13:35:52

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 09:23:31

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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-10-09T11:22:19', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '908403b8-f3d4-441c-82f3-d546774e8c6c'	System	09 Oct 2020 15:22:24
User entered 'No (N)'	System	09 Oct 2020 15:22:24

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 09:23:31

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-10-09T11:22:21', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '908403b8-f3d4-441c-82f3-d546774e8c6c'	System	09 Oct 2020 15:22:24
User entered '09 Oct 2020 11:22'	System	09 Oct 2020 15:22:24

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 09:23:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '08 Oct 2020 12:00'	System	08 Oct 2020 13:35:52

US3432260

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(18)

Generated On: 26 Nov 2020 09:23:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '09 Oct 2020 11:59'	System	08 Oct 2020 13:35:52

US3432260

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	01 Oct 2020 20:52:24

US3432260

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '28 Sep 2020'	Phoebe Cunningham (b) (4)	01 Oct 2020 20:52:24

US3432260

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	01 Oct 2020 20:52:24

US3432260

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	01 Oct 2020 20:52:24

US3432260

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	01 Oct 2020 20:52:29

US3432260

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 20:52:29

US3432260

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Oct 2020 18:45:39

US3432260

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:31

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '5 Oct 2020'	(b) (4), (b) (6)	05 Oct 2020 18:45:39

US3432260

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Oct 2020 18:45:39

US3432260

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	05 Oct 2020 18:45:39

US3432260

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	12 Oct 2020 16:44:02

US3432260

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Oct 2020 16:44:02

US3432260

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 17:38:01

US3432260

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 17:38:01

US3432260

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	13 Oct 2020 17:38:01

US3432260

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:23:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 17:38:01

US3432260

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Oct 2020 15:36:07

US3432260

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Oct 2020 15:36:07

US3432260

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Oct 2020 15:36:18

US3432260

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '24 Oct 2020'	(b) (4), (b) (6)	24 Oct 2020 15:36:18

US3432260

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	24 Oct 2020 15:36:18

US3432260

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	24 Oct 2020 15:36:18

US3432260

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Oct 2020 15:37:12

US3432260

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Oct 2020'	(b) (4), (b) (6)	24 Oct 2020 15:37:12

US3432260

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '10:33'	(b) (4), (b) (6)	24 Oct 2020 15:37:12

US3432260

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '24 Oct 2020 10:33'	System	24 Oct 2020 15:37:12

US3432260

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.3' F	(b) (4), (b) (6)	24 Oct 2020 15:37:12

US3432260

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Other (Other)'	(b) (4), (b) (6)	24 Oct 2020 15:37:12

US3432260

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

[If Other, specify](#)

Audit	User	Time (GMT)
User entered 'infrared'	(b) (4), (b) (6)	24 Oct 2020 15:37:12

US3432260

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '66'	(b) (4), (b) (6)	24 Oct 2020 15:37:12

US3432260

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	24 Oct 2020 15:37:12

US3432260

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '14'	(b) (4), (b) (6)	24 Oct 2020 15:37:12

US3432260

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	24 Oct 2020 15:37:12

US3432260

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '117'	(b) (4), (b) (6)	24 Oct 2020 15:37:12

US3432260

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Oct 2020 15:37:12

US3432260

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '70'	(b) (4), (b) (6)	24 Oct 2020 15:37:12

US3432260

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	24 Oct 2020 15:37:12

US3432260

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	24 Oct 2020 15:37:39

US3432260

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:31

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Oct 2020 15:37:39

US3432260

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Oct 2020 15:37:49

US3432260

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '24 Oct 2020'	(b) (4), (b) (6)	24 Oct 2020 15:37:49

US3432260

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:31

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered '11:17'	(b) (4), (b) (6)	24 Oct 2020 15:37:49

US3432260

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '24 Oct 2020 11:17'	System	24 Oct 2020 15:37:49

US3432260

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Oct 2020 15:37:52

US3432260

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:23:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Oct 2020 15:37:52

US3432260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 16:57:29
User entered 'Day 64'	System	24 Aug 2020 16:57:29

US3432260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-10-28T11:59:25', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '1c9fbf61-5e23-4a96-94b2-31cb9b3e7ae5'	System	28 Oct 2020 15:59:33
User entered 'No (N)'	System	28 Oct 2020 15:59:33

US3432260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

Have you been exposed to someone with 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 (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-10-28T11:59:28', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '1c9fbf61-5e23-4a96-94b2-31cb9b3e7ae5'	System	28 Oct 2020 15:59:33
User entered 'No (N)'	System	28 Oct 2020 15:59:33

US3432260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (E065FF5F-AEDE-4261-902E-FF7B12C928A4)', Time: '2020-10-28T11:59:31', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '1c9fbf61-5e23-4a96-94b2-31cb9b3e7ae5' User entered '28 Oct 2020 11:59:31'	System	28 Oct 2020 15:59:33
	System	28 Oct 2020 15:59:33

US3432260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 16:57:29
User entered '24 Oct 2020 00:01'	System	24 Aug 2020 16:57:29

US3432260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 16:57:29
User entered '28 Oct 2020 23:59'	System	24 Aug 2020 16:57:29

US3432260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 16:57:29
User entered 'Day 71'	System	24 Aug 2020 16:57:29

US3432260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[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 (F2EFB41A-C73C-49F4-BF33-EF9D67F82E52)', Time: '2020-11-04T14:56:38', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '865627a7-3ff5-4b77-a1ee-ef78060e8b02'	System	04 Nov 2020 19:56:56
User entered 'Yes (Y)'	System	04 Nov 2020 19:56:56

US3432260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

Have you been exposed to someone with 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 (F2EFB41A-C73C-49F4-BF33-EF9D67F82E52)', Time: '2020-11-04T14:56:34', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '865627a7-3ff5-4b77-a1ee-ef78060e8b02'	System	04 Nov 2020 19:56:56
User entered 'No (N)'	System	04 Nov 2020 19:56:56

US3432260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F2EFB41A-C73C-49F4-BF33-EF9D67F82E52)', Time: '2020-11-04T14:56:31', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '865627a7-3ff5-4b77-a1ee-ef78060e8b02'	System	04 Nov 2020 19:56:56
User entered 'No (N)'	System	04 Nov 2020 19:56:56

US3432260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F2EFB41A-C73C-49F4-BF33-EF9D67F82E52)', Time: '2020-11-04T14:56:28', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '865627a7-3ff5-4b77-a1ee-ef78060e8b02'	System	04 Nov 2020 19:56:56
User entered 'Yes (Y)'	System	04 Nov 2020 19:56:56

US3432260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Please 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 (F2EFB41A-C73C-49F4-BF33-EF9D67F82E52)', Time: '2020-11-04T14:56:42', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '865627a7-3ff5-4b77-a1ee-ef78060e8b02'	System	04 Nov 2020 19:56:56
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	04 Nov 2020 19:56:56

US3432260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F2EFB41A-C73C-49F4-BF33-EF9D67F82E52)', Time: '2020-11-04T14:56:45', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: '865627a7-3ff5-4b77-a1ee-ef78060e8b02'	System	04 Nov 2020 19:56:56
User entered '04 Nov 2020 14:56:45'	System	04 Nov 2020 19:56:56

US3432260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 16:57:29
User entered '31 Oct 2020 00:01'	System	24 Aug 2020 16:57:29

US3432260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 16:57:29
User entered '04 Nov 2020 23:59'	System	24 Aug 2020 16:57:29

US3432260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 16:57:29
User entered 'Day 78'	System	24 Aug 2020 16:57:29

US3432260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[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 (F2EFB41A-C73C-49F4-BF33-EF9D67F82E52)', Time: '2020-11-10T17:59:52', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'daca5b6f-5368-4aa2-bdc6-717be3f0337c' User entered 'No (N)'	System	10 Nov 2020 23:00:17
	System	10 Nov 2020 23:00:17

US3432260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

Have you been exposed to someone with 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 (F2EFB41A-C73C-49F4-BF33-EF9D67F82E52)', Time: '2020-11-10T17:59:59', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'daca5b6f-5368-4aa2-bdc6-717be3f0337c' User entered 'Yes (Y)'	System	10 Nov 2020 23:00:17
	System	10 Nov 2020 23:00:17

US3432260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Please 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 (F2EFB41A-C73C-49F4-BF33-EF9D67F82E52)', Time: '2020-11-10T18:00:05', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'daca5b6f-5368-4aa2-bdc6-717be3f0337c'	System	10 Nov 2020 23:00:17
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	10 Nov 2020 23:00:17

US3432260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F2EFB41A-C73C-49F4-BF33-EF9D67F82E52)', Time: '2020-11-10T18:00:09', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'daca5b6f-5368-4aa2-bdc6-717be3f0337c' User entered '10 Nov 2020 18:00:09'	System	10 Nov 2020 23:00:17
	System	10 Nov 2020 23:00:17

US3432260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 16:57:29
User entered '07 Nov 2020 00:01'	System	24 Aug 2020 16:57:29

US3432260

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	24 Aug 2020 16:57:29
User entered '11 Nov 2020 23:59'	System	24 Aug 2020 16:57:29

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '21 Oct 2020 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '25 Oct 2020 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '28 Oct 2020 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '01 Nov 2020 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '04 Nov 2020 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '08 Nov 2020 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '11 Nov 2020 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '15 Nov 2020 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[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 (F2EFB41A-C73C-49F4-BF33-EF9D67F82E52)', Time: '2020-11-21T06:04:29', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'fab37ca1-3bfa-4987-8db7-f0f461163589'	System	21 Nov 2020 11:05:22
User entered 'Yes (Y)'	System	21 Nov 2020 11:05:22

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

Have you been exposed to someone with 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 (F2EFB41A-C73C-49F4-BF33-EF9D67F82E52)', Time: '2020-11-21T06:04:40', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'fab37ca1-3bfa-4987-8db7-f0f461163589'	System	21 Nov 2020 11:05:22
User entered 'No (N)'	System	21 Nov 2020 11:05:22

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F2EFB41A-C73C-49F4-BF33-EF9D67F82E52)', Time: '2020-11-21T06:04:47', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'fab37ca1-3bfa-4987-8db7-f0f461163589'	System	21 Nov 2020 11:05:22
User entered 'Yes (Y)'	System	21 Nov 2020 11:05:22

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Fever \(Temperature \$\geq\$ 100.4°F/38°C\)](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F2EFB41A-C73C-49F4-BF33-EF9D67F82E52)', Time: '2020-11-21T06:04:58', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'fab37ca1-3bfa-4987-8db7-f0f461163589' User entered '0'	System	21 Nov 2020 11:05:22

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F2EFB41A-C73C-49F4-BF33-EF9D67F82E52)', Time: '2020-11-21T06:04:58', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'fab37ca1-3bfa-4987-8db7-f0f461163589'	System	21 Nov 2020 11:05:22
User entered '0'	System	21 Nov 2020 11:05:22

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F2EFB41A-C73C-49F4-BF33-EF9D67F82E52)', Time: '2020-11-21T06:04:58', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'fab37ca1-3bfa-4987-8db7-f0f461163589' User entered '0'	System	21 Nov 2020 11:05:22
	System	21 Nov 2020 11:05:22

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F2EFB41A-C73C-49F4-BF33-EF9D67F82E52)', Time: '2020-11-21T06:04:58', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'fab37ca1-3bfa-4987-8db7-f0f461163589' User entered '0'	System	21 Nov 2020 11:05:22

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F2EFB41A-C73C-49F4-BF33-EF9D67F82E52)', Time: '2020-11-21T06:04:58', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'fab37ca1-3bfa-4987-8db7-f0f461163589' User entered '0'	System	21 Nov 2020 11:05:22

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F2EFB41A-C73C-49F4-BF33-EF9D67F82E52)', Time: '2020-11-21T06:04:58', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'fab37ca1-3bfa-4987-8db7-f0f461163589' User entered '0'	System	21 Nov 2020 11:05:22
	System	21 Nov 2020 11:05:22

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F2EFB41A-C73C-49F4-BF33-EF9D67F82E52)', Time: '2020-11-21T06:04:58', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'fab37ca1-3bfa-4987-8db7-f0f461163589' User entered '0'	System	21 Nov 2020 11:05:22

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F2EFB41A-C73C-49F4-BF33-EF9D67F82E52)', Time: '2020-11-21T06:04:58', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'fab37ca1-3bfa-4987-8db7-f0f461163589' User entered '0'	System	21 Nov 2020 11:05:22

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F2EFB41A-C73C-49F4-BF33-EF9D67F82E52)', Time: '2020-11-21T06:04:58', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'fab37ca1-3bfa-4987-8db7-f0f461163589' User entered '0'	System	21 Nov 2020 11:05:22

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F2EFB41A-C73C-49F4-BF33-EF9D67F82E52)', Time: '2020-11-21T06:04:58', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'fab37ca1-3bfa-4987-8db7-f0f461163589' User entered '0'	System	21 Nov 2020 11:05:22

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F2EFB41A-C73C-49F4-BF33-EF9D67F82E52)', Time: '2020-11-21T06:04:58', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'fab37ca1-3bfa-4987-8db7-f0f461163589' User entered '0'	System	21 Nov 2020 11:05:22

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F2EFB41A-C73C-49F4-BF33-EF9D67F82E52)', Time: '2020-11-21T06:04:58', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'fab37ca1-3bfa-4987-8db7-f0f461163589'	System	21 Nov 2020 11:05:22
User entered '0'	System	21 Nov 2020 11:05:22

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F2EFB41A-C73C-49F4-BF33-EF9D67F82E52)', Time: '2020-11-21T06:04:58', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'fab37ca1-3bfa-4987-8db7-f0f461163589' User entered '0'	System	21 Nov 2020 11:05:22

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F2EFB41A-C73C-49F4-BF33-EF9D67F82E52)', Time: '2020-11-21T06:04:58', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'fab37ca1-3bfa-4987-8db7-f0f461163589' User entered '0'	System	21 Nov 2020 11:05:22
	System	21 Nov 2020 11:05:22

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F2EFB41A-C73C-49F4-BF33-EF9D67F82E52)', Time: '2020-11-21T06:04:58', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'fab37ca1-3bfa-4987-8db7-f0f461163589'	System	21 Nov 2020 11:05:22
User entered '1'	System	21 Nov 2020 11:05:22

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F2EFB41A-C73C-49F4-BF33-EF9D67F82E52)', Time: '2020-11-21T06:04:58', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'fab37ca1-3bfa-4987-8db7-f0f461163589'	System	21 Nov 2020 11:05:22
User entered '0'	System	21 Nov 2020 11:05:22

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F2EFB41A-C73C-49F4-BF33-EF9D67F82E52)', Time: '2020-11-21T06:04:58', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'fab37ca1-3bfa-4987-8db7-f0f461163589'	System	21 Nov 2020 11:05:22
User entered '1'	System	21 Nov 2020 11:05:22

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Please 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 (F2EFB41A-C73C-49F4-BF33-EF9D67F82E52)', Time: '2020-11-21T06:05:01', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'fab37ca1-3bfa-4987-8db7-f0f461163589'	System	21 Nov 2020 11:05:22
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Nov 2020 11:05:22

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F2EFB41A-C73C-49F4-BF33-EF9D67F82E52)', Time: '2020-11-21T06:05:06', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'fab37ca1-3bfa-4987-8db7-f0f461163589'	System	21 Nov 2020 11:05:22
User entered 'No (N)'	System	21 Nov 2020 11:05:22

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F2EFB41A-C73C-49F4-BF33-EF9D67F82E52)', Time: '2020-11-21T06:05:11', User OID: 'PatientReportedOutcome (US3432260)', ODM File OID: 'fab37ca1-3bfa-4987-8db7-f0f461163589' User entered '21 Nov 2020 06:05:11'	System	21 Nov 2020 11:05:22
	System	21 Nov 2020 11:05:22

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '18 Nov 2020 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '22 Nov 2020 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '25 Nov 2020 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '29 Nov 2020 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '02 Dec 2020 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '06 Dec 2020 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '09 Dec 2020 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '13 Dec 2020 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '16 Dec 2020 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '20 Dec 2020 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '23 Dec 2020 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '27 Dec 2020 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '30 Dec 2020 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '03 Jan 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '06 Jan 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '10 Jan 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '13 Jan 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '17 Jan 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '20 Jan 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '24 Jan 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '27 Jan 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '31 Jan 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '03 Feb 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '07 Feb 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '10 Feb 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '14 Feb 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '17 Feb 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '21 Feb 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '24 Feb 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '28 Feb 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '03 Mar 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '07 Mar 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '10 Mar 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '14 Mar 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '17 Mar 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '21 Mar 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '24 Mar 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '28 Mar 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '31 Mar 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '04 Apr 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '07 Apr 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '11 Apr 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '14 Apr 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '18 Apr 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '21 Apr 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '25 Apr 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '28 Apr 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '02 May 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '05 May 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '09 May 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '12 May 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '16 May 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '19 May 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '23 May 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '26 May 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '30 May 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '02 Jun 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '06 Jun 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '09 Jun 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '13 Jun 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '16 Jun 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '20 Jun 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '23 Jun 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '27 Jun 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '30 Jun 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '04 Jul 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '07 Jul 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '11 Jul 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '14 Jul 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '18 Jul 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '21 Jul 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '25 Jul 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '28 Jul 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '01 Aug 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '04 Aug 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '08 Aug 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '11 Aug 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '15 Aug 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '18 Aug 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '22 Aug 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '25 Aug 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '29 Aug 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '01 Sep 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '05 Sep 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '08 Sep 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '12 Sep 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '15 Sep 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '19 Sep 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '22 Sep 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '26 Sep 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '29 Sep 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '03 Oct 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '06 Oct 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '10 Oct 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '13 Oct 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '17 Oct 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '20 Oct 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '24 Oct 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '27 Oct 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '31 Oct 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '03 Nov 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '07 Nov 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '10 Nov 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '14 Nov 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '17 Nov 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '21 Nov 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '24 Nov 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '28 Nov 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '01 Dec 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '05 Dec 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '08 Dec 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '12 Dec 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '15 Dec 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '19 Dec 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '22 Dec 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '26 Dec 2021 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '29 Dec 2021 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '02 Jan 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '05 Jan 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '09 Jan 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '12 Jan 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '16 Jan 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '19 Jan 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '23 Jan 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '26 Jan 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '30 Jan 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '02 Feb 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '06 Feb 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '09 Feb 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '13 Feb 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '16 Feb 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '20 Feb 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '23 Feb 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '27 Feb 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '02 Mar 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '06 Mar 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '09 Mar 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '13 Mar 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '16 Mar 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '20 Mar 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '23 Mar 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '27 Mar 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '30 Mar 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '03 Apr 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '06 Apr 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '10 Apr 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '13 Apr 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '17 Apr 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '20 Apr 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '24 Apr 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '27 Apr 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '01 May 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '04 May 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '08 May 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '11 May 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '15 May 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '18 May 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '22 May 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '25 May 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '29 May 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '01 Jun 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '05 Jun 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '08 Jun 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '12 Jun 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '15 Jun 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '19 Jun 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '22 Jun 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '26 Jun 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '29 Jun 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '03 Jul 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '06 Jul 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '10 Jul 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '13 Jul 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '17 Jul 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '20 Jul 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '24 Jul 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '27 Jul 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '31 Jul 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '03 Aug 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '07 Aug 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '10 Aug 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '14 Aug 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '17 Aug 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '21 Aug 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '24 Aug 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '28 Aug 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '31 Aug 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '04 Sep 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '07 Sep 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '11 Sep 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '14 Sep 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '18 Sep 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '21 Sep 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '25 Sep 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '28 Sep 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '02 Oct 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '05 Oct 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '09 Oct 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '12 Oct 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '16 Oct 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '19 Oct 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '23 Oct 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '26 Oct 2022 00:01'	System	20 Nov 2020 01:44:19

US3432260

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:23:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 01:44:19
Amendment Manager: User entered '30 Oct 2022 23:59'	System	20 Nov 2020 01:44:19

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:23:31

[Date of Contact](#)

Audit	User	Time (GMT)
User entered '21 Nov 2020'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:41:36

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:23:31

[Time of Contact](#)

Audit	User	Time (GMT)
User entered '10:30'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:41:36

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:23:31

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
User entered '21 Nov 2020 10:30'	System	21 Nov 2020 18:41:36

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:23:31

[Type of Contact](#)

Audit	User	Time (GMT)
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:41:36

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:23:31

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:41:36

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 1 (Day 1)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:15

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:31

[Date](#)

Audit	User	Time (GMT)
User entered '14 Nov 2020'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:15

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:15

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:31

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:15

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Nov 2020 18:42:15

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:31

[Temperature](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:15

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:31

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:15

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:31

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:15

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:15

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:15

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:31

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:15

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:15

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:31

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:15

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:31

[Headache](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:15

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:15

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:15

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:15

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:15

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:31

[Nausea](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:15

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:31

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:15

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:31

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:15

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (1)

Generated On: 26 Nov 2020 09:23:31

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:15

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 2 (Day 2)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:52

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:31

[Date](#)

Audit	User	Time (GMT)
User entered '15 Nov 2020'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:52

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:52

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:31

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:52

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Nov 2020 18:42:52

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:31

[Temperature](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:52

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:31

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:52

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:31

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:52

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:52

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:52

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:31

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:52

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:52

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:31

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:52

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:31

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:52

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:52

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:52

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:52

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:52

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:31

[Nausea](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:52

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:31

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:52

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:31

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:52

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (2)

Generated On: 26 Nov 2020 09:23:31

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:42:52

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 3 (Day 3)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:43:27

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:31

[Date](#)

Audit	User	Time (GMT)
User entered '16 Nov 2020'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:43:27

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:43:27

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:31

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:43:27

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Nov 2020 18:43:27

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:31

[Temperature](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:43:27

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:31

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:43:27

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:31

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:43:27

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:43:27

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:43:27

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:31

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:43:27

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:43:27

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:31

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:43:27

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:31

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:43:27

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:43:27

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:43:27

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:43:27

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:43:27

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:31

[Nausea](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:43:27

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:31

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:43:27

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:31

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:43:27

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (3)

Generated On: 26 Nov 2020 09:23:31

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:43:27

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 4 (Day 4)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:02

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:31

[Date](#)

Audit	User	Time (GMT)
User entered '17 Nov 2020'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:02

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:02

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:31

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:02

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Nov 2020 18:44:02

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:31

[Temperature](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:02

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:31

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:02

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:31

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:02

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:02

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:02

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:31

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:02

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:02

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:31

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:02

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:31

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:02

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:02

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:02

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:02

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:02

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:31

[Nausea](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:02

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:31

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:02

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:31

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:02

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (4)

Generated On: 26 Nov 2020 09:23:31

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:02

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 5 (Day 5)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:37

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:31

[Date](#)

Audit	User	Time (GMT)
User entered '18 Nov 2020'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:37

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:37

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:31

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:37

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Nov 2020 18:44:37

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:31

[Temperature](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:37

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:31

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:37

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:31

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:37

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:37

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:37

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:31

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:37

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:37

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:31

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:37

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:31

[Headache](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:37

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:37

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:37

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:37

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:37

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:31

[Nausea](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:37

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:31

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:37

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:31

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:37

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (5)

Generated On: 26 Nov 2020 09:23:31

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:44:37

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 6 (Day 6)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:12

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:31

[Date](#)

Audit	User	Time (GMT)
User entered '19 Nov 2020'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:12

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:12

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:31

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:12

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Nov 2020 18:45:12

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:31

[Temperature](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:12

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:31

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:12

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:31

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:12

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:12

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:12

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:31

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:12

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:12

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:31

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:12

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:31

[Headache](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:12

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:12

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:12

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:12

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:12

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:31

[Nausea](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:12

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:31

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:12

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:31

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:12

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (6)

Generated On: 26 Nov 2020 09:23:31

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:12

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 7 (Day 7)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:47

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:31

[Date](#)

Audit	User	Time (GMT)
User entered '20 Nov 2020'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:47

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:47

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:31

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:47

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Nov 2020 18:45:47

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:31

[Temperature](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:47

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:31

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:47

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:31

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:47

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:47

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:47

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:31

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:47

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:31

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:47

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:31

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:47

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:31

[Headache](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:47

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:47

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:47

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:47

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:47

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:31

[Nausea](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:47

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:31

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:47

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:31

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:47

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (7)

Generated On: 26 Nov 2020 09:23:31

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:45:47

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 8 (Day 8)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:46:36

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:31

[Date](#)

Audit	User	Time (GMT)
User entered '21 Nov 2020'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:46:36

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:46:36

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:31

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '99'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:46:36

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	21 Nov 2020 18:46:36

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:31

[Temperature](#)

Audit	User	Time (GMT)
User entered '37.5' C	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:46:36

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:31

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:46:36

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:31

[Cough](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:46:36

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:46:36

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:46:36

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:31

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:46:36

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:46:36

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:31

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:46:36

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:31

[Headache](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:46:36

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:46:36

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:46:36

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:46:36

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:46:36

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:31

[Nausea](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:46:36

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:31

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:46:36

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:31

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:46:36

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (8)

Generated On: 26 Nov 2020 09:23:31

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:46:36

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 9 (Day 9)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:32:41

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:31

[Date](#)

Audit	User	Time (GMT)
User entered '22 Nov 2020'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:32:41

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '1'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:32:41

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:31

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered empty.	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:32:41

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 21:32:41

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:31

[Temperature](#)

Audit	User	Time (GMT)
User entered empty.	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:32:41

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:31

[Chills](#)

Audit	User	Time (GMT)
User entered empty.	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:32:41

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:31

[Cough](#)

Audit	User	Time (GMT)
User entered empty.	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:32:41

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered empty.	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:32:41

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered empty.	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:32:41

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:31

[Fatigue](#)

Audit	User	Time (GMT)
User entered empty.	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:32:41

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered empty.	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:32:41

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:31

[Body Aches](#)

Audit	User	Time (GMT)
User entered empty.	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:32:41

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:31

[Headache](#)

Audit	User	Time (GMT)
User entered empty.	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:32:41

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered empty.	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:32:41

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered empty.	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:32:41

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered empty.	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:32:41

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered empty.	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:32:41

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:31

[Nausea](#)

Audit	User	Time (GMT)
User entered empty.	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:32:41

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:31

[Vomiting](#)

Audit	User	Time (GMT)
User entered empty.	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:32:41

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:31

[Diarrhea](#)

Audit	User	Time (GMT)
User entered empty.	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:32:41

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (9)

Generated On: 26 Nov 2020 09:23:31

[Sore Throat](#)

Audit	User	Time (GMT)
User entered empty.	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:32:41

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:23:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 10 (Day 10)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:33:30

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:23:31

[Date](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:33:30

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:23:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:33:30

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:23:31

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:33:30

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:23:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	24 Nov 2020 21:33:30

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:23:31

[Temperature](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:33:30

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:23:31

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:33:30

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:23:31

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:33:30

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:23:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:33:30

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:23:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:33:30

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:23:31

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:33:30

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:23:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:33:30

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:23:31

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:33:30

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:23:31

[Headache](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:33:30

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:23:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:33:30

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:23:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:33:30

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:23:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:33:30

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:23:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:33:30

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:23:31

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:33:30

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:23:31

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:33:30

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:23:31

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:33:30

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (10)

Generated On: 26 Nov 2020 09:23:31

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:33:30

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:23:31

[Symptom Day](#)

Audit	User	Time (GMT)
User entered 'Day 11 (Day 11)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:34:16

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:23:31

[Date](#)

Audit	User	Time (GMT)
User entered '24 Nov 2020'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:34:16

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:23:31

[Assessment Not Done](#)

Audit	User	Time (GMT)
User entered '0'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:34:16

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:23:31

[O2 Saturation](#)

Audit	User	Time (GMT)
User entered '99'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:34:16

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:23:31

[O2 Saturation Units](#)

Audit	User	Time (GMT)
User entered '%'	System	24 Nov 2020 21:34:16

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:23:31

[Temperature](#)

Audit	User	Time (GMT)
User entered '98.9' F	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:34:16

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:23:31

[Chills](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:34:16

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:23:31

[Cough](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:34:16

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:23:31

[Shortness of Breath](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:34:16

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:23:31

[Difficulty Breathing](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:34:16

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:23:31

[Fatigue](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:34:16

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:23:31

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:34:16

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:23:31

[Body Aches](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:34:16

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:23:31

[Headache](#)

Audit	User	Time (GMT)
User entered 'Moderate (Moderate)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:34:16

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:23:31

[New Loss of Taste](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:34:16

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:23:31

[New Loss of Smell](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:34:16

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:23:31

[Nasal Congestion](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:34:16

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:23:31

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:34:16

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:23:31

[Nausea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:34:16

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:23:31

[Vomiting](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:34:16

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:23:31

[Diarrhea](#)

Audit	User	Time (GMT)
User entered 'None (None)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:34:16

US3432260

Folder: Covid-19 Assessment 21 Nov 2020

Form: Symptom Log (11)

Generated On: 26 Nov 2020 09:23:31

[Sore Throat](#)

Audit	User	Time (GMT)
User entered 'Mild (Mild)'	Austin Kim (b) (4) (b) (4)	24 Nov 2020 21:34:16

US3432260

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:46:48

US3432260

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '21 Nov 2020'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:46:48

US3432260

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:46:48

US3432260

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:23:31

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	21 Nov 2020 18:46:48

US3432260

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:47:28

US3432260

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '21 Nov 2020'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:47:28

US3432260

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '10:15'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:47:28

US3432260

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '21 Nov 2020 10:15'	System	21 Nov 2020 18:47:28

US3432260

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jun Bai Park Chang	21 Nov 2020 18:47:28
DataPoint set to visible.	(b) (4) System	21 Nov 2020 18:46:48

US3432260

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Jun Bai Park Chang	21 Nov 2020 18:47:28
DataPoint set to visible.	(b) (4) System	21 Nov 2020 18:46:48

US3432260

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '37.5' C	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:47:28

US3432260

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:47:28

US3432260

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:47:28

US3432260

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '79'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:47:28

US3432260

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	21 Nov 2020 18:47:28

US3432260

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '16'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:47:28

US3432260

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	21 Nov 2020 18:47:28

US3432260

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '110'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:47:28

US3432260

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Nov 2020 18:47:28

US3432260

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '79'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:47:28

US3432260

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:23:31

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	21 Nov 2020 18:47:28

US3432260

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:47:41

US3432260

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:23:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '21 Nov 2020'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:47:41

US3432260

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:23:31

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:47:48

US3432260

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 26 Nov 2020 09:23:31

[Date of Collection](#)

Audit	User	Time (GMT)
User entered '21 Nov 2020'	Jun Bai Park Chang (b) (4)	21 Nov 2020 18:47:48

US3432260

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:23:31

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	02 Sep 2020 00:10:30

US3432260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:31

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: Therapeutic and nontherapeutic effects (excl toxicity), HLT: Therapeutic and nontherapeutic responses, PT: Reactogenicity event, LLT: Reactogenicity event - version MedDRA\23.0.	Coder Import (b) (4)	24 Nov 2020 21:08:57
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	24 Nov 2020 21:08:57
Data point term sent to Coder	System	24 Nov 2020 21:01:38
Query 'For coding purposes, please split REACTOGENICITY SYNDROME (INTERMITTENT NAUSEA AND HEADACHE) into separate entries. 1. Intermittent Nausea and 2. Intermittent Headache' canceled (Site from System).	Coder Import (b) (4)	24 Nov 2020 21:01:02
User closed query 'Per DM CLR: Please review and update to record each solicited event individually. Please update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 04:24:32
User closed query 'Per MM, Please update the specific reactogenecity term.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 16:59:00
User opened query 'For coding purposes, please split REACTOGENICITY SYNDROME (INTERMITTENT NAUSEA AND HEADACHE) into separate entries. 1. Intermittent Nausea and 2. Intermittent Headache' (Site from System).	Coder Import (b) (4)	11 Nov 2020 12:01:30
Query 'Per DM CLR: Please review and update to record each solicited event individually. Please update as appropriate or provide clarification.' answered with 'this is part of reacto syndrome which is one term' (Site from DM).	Monica Feeley (b) (4)	05 Nov 2020 20:45:10
User opened query 'Per DM CLR: Please review and update to record each solicited event individually. Please update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 23:06:25
User coded data point as SOC: General disorders and administration site conditions, HLGT: Therapeutic and nontherapeutic effects (excl toxicity), HLT: Therapeutic and nontherapeutic responses, PT: Reactogenicity event, LLT: Reactogenicity event - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 09:08:33
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 09:08:33

v6.020 DTW (1102)

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US3432260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:31

[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	19 Oct 2020 20:44:34
Query 'Per MM, Please update the specific reactogenicity term.' answered with 'updated' (Site from DM).	Bruce Bausk (b) (4)	19 Oct 2020 20:44:19
Coding entries removed.	(b) (4)	
	Bruce Bausk (b) (4)	19 Oct 2020 20:44:14
	(b) (4)	
User entered 'REACTOGENICITY SYNDROME (intermittent nausea and headache)' reason for change: Data Entry Error	Bruce Bausk (b) (4)	19 Oct 2020 20:44:14
	(b) (4)	
User opened query 'Per MM, Please update the specific reactogenicity term.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 09:54:22
User coded data point as SOC: General disorders and administration site conditions, HLGT: Therapeutic and nontherapeutic effects (excl toxicity), HLT: Therapeutic and nontherapeutic responses, PT: Reactogenicity event, LLT: Reactogenicity event - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 00:12:38
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	02 Sep 2020 00:12:38
	(b) (4)	
Data point term sent to Coder	System	02 Sep 2020 00:12:19
User entered 'reactogenicity syndrome'	Xhoi Mitre (b) (4)	02 Sep 2020 00:11:45
	(b) (4)	

US3432260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	02 Sep 2020 00:11:45

US3432260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	02 Sep 2020 00:11:45

US3432260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	02 Sep 2020 00:11:45

US3432260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '26 Aug 2020'	Xhoi Mitre (b) (4) (b) (4)	02 Sep 2020 00:11:45

US3432260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:31

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	02 Sep 2020 00:11:45

US3432260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 00:11:45

US3432260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:31

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Phoebe Cunningham (b) (4)	27 Oct 2020 21:27:23
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	02 Sep 2020 00:11:45

US3432260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	27 Oct 2020 21:27:35
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	27 Oct 2020 21:27:35
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	27 Oct 2020 21:27:23
User entered '5 Sep 2020' reason for change: Data Entry Error	Phoebe Cunningham (b) (4)	27 Oct 2020 21:27:23
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	02 Sep 2020 00:11:45

US3432260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:31

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	02 Sep 2020 00:11:45

US3432260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Sep 2020 00:11:45

US3432260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:31

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	Xhoi Mitre (b) (4) (b) (4)	02 Sep 2020 00:11:45

US3432260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	02 Sep 2020 00:11:45

US3432260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:31

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	02 Sep 2020 00:11:45

US3432260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:31

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	02 Sep 2020 00:11:45

US3432260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	02 Sep 2020 00:11:45

US3432260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:31

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	02 Sep 2020 00:11:45

US3432260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:31

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	02 Sep 2020 00:11:45

US3432260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	02 Sep 2020 00:11:45

US3432260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	02 Sep 2020 00:11:45

US3432260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	02 Sep 2020 00:11:45

US3432260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	02 Sep 2020 00:11:45

US3432260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:31

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	02 Sep 2020 00:11:45

US3432260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	Xhoi Mitre (b) (4) (b) (4)	02 Sep 2020 00:11:45

US3432260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4) (b) (4)	02 Sep 2020 00:11:45

US3432260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Xhoi Mitre (b) (4) (b) (4)	02 Sep 2020 00:11:45

US3432260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:31

[None](#)

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	02 Sep 2020 00:11:45

US3432260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Xhoi Mitre (b) (4) (b) (4)	02 Sep 2020 00:11:45

US3432260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	02 Sep 2020 00:11:45

US3432260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:31

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Phoebe Cunningham (b) (4)	27 Oct 2020 21:27:35
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Xhoi Mitre (b) (4) (b) (4)	02 Sep 2020 00:11:45

US3432260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:31

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	02 Sep 2020 00:11:45

US3432260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:31

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	02 Sep 2020 00:11:45

US3432260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Sep 2020 00:11:45

US3432260

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:23:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Sep 2020 00:11:45

US3432260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:31

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per MM, please confirm if the subject was evaluated for COVID-19' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 13:20:27
Query 'Per MM, please confirm if the subject was evaluated for COVID-19' answered with 'yes. had test that was negative (sept 4)' (Site from DM).	Monica Feeley (b) (4)	05 Nov 2020 20:44:47
User opened query 'Per MM, please confirm if the subject was evaluated for COVID-19' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 08:55:53
User closed query 'Per MM, Please update the term to a medical diagnosis' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 12:38:11
User closed query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon of CHRONIC SINUSITIS. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 12:38:07
Query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon of CHRONIC SINUSITIS. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' answered with 'participant has sinus infection. no MH. ' (Site from DM).	Monica Feeley (b) (4)	07 Oct 2020 14:14:54
Query 'Per MM, Please update the term to a medical diagnosis' answered with 'sinus infection is a medical diagnosis' (Site from DM).	Monica Feeley (b) (4)	07 Oct 2020 14:14:35
User opened query 'Per MM, Please update the term to a medical diagnosis' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 09:54:38
User opened query 'Per DM CLR: Please verify if this event is a worsening of the ongoing MH conditon of CHRONIC SINUSITIS. If yes, update the event term to reflect 'worsening' and update any corresponding CMs, as applicable. Otherwise, provide clarifications. ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 02:13:57
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Sinus infection - version MedDRA\23.0.	Coder Import (b) (4)	09 Sep 2020 01:05:55

US3432260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:31

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	09 Sep 2020 01:05:55
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	09 Sep 2020 01:04:37
User entered 'Sinus Infection'	Xhoi Mitre (b) (4)	09 Sep 2020 01:04:31
	(b) (4)	

US3432260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	09 Sep 2020 01:04:31

US3432260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	09 Sep 2020 01:04:31

US3432260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	09 Sep 2020 01:04:31

US3432260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '02 Sep 2020'	Xhoi Mitre (b) (4) (b) (4)	09 Sep 2020 01:04:31

US3432260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:31

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	09 Sep 2020 01:04:31

US3432260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 01:04:31

US3432260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:31

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 21:45:34
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	09 Sep 2020 01:04:31

US3432260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	21 Sep 2020 21:45:42
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	21 Sep 2020 21:45:42
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	21 Sep 2020 21:45:34
User entered '12 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 21:45:34
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	09 Sep 2020 01:04:31

US3432260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:31

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	09 Sep 2020 01:04:31

US3432260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 01:04:31

US3432260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:31

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Xhoi Mitre (b) (4) (b) (4)	09 Sep 2020 01:04:31

US3432260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	09 Sep 2020 01:04:31

US3432260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:31

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	09 Sep 2020 01:04:31

US3432260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:31

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	09 Sep 2020 01:04:31

US3432260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	09 Sep 2020 01:04:31

US3432260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:31

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	09 Sep 2020 01:04:31

US3432260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:31

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	09 Sep 2020 01:04:31

US3432260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	09 Sep 2020 01:04:31

US3432260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	09 Sep 2020 01:04:31

US3432260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	09 Sep 2020 01:04:31

US3432260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	09 Sep 2020 01:04:31

US3432260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:31

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	09 Sep 2020 01:04:31

US3432260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4) (b) (4)	09 Sep 2020 01:04:31

US3432260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4) (b) (4)	09 Sep 2020 01:04:31

US3432260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Xhoi Mitre (b) (4) (b) (4)	09 Sep 2020 01:04:31

US3432260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:31

[None](#)

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	09 Sep 2020 01:04:31

US3432260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Xhoi Mitre (b) (4) (b) (4)	09 Sep 2020 01:04:31

US3432260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	09 Sep 2020 01:04:31

US3432260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:31

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 21:45:42
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Xhoi Mitre (b) (4)	09 Sep 2020 01:04:31

US3432260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:31

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	09 Sep 2020 01:04:31

US3432260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:31

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	09 Sep 2020 01:04:31

US3432260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Sep 2020 01:04:31

US3432260

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:23:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Sep 2020 01:04:31

US3432260

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:03:16
User entered 'USA-US078-2020-mRNA-1273-P301000010'	System	06 Nov 2020 19:03:12
User entered 'New'	(b) (4), (b) (6)	06 Nov 2020 19:03:12

US3432260

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:51:51
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal fusion surgery, LLT: Fusion cervical spine - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 21:09:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	05 Nov 2020 21:09:23
Data point term sent to Coder	System	05 Nov 2020 20:52:59
User entered 'cervical fusion c5-c6'	Monica Feeley (b) (4) (b) (4)	05 Nov 2020 20:52:31

US3432260

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	05 Nov 2020 20:52:31

US3432260

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	05 Nov 2020 20:52:31

US3432260

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	05 Nov 2020 20:52:31

US3432260

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '04 Nov 2020'	Monica Feeley (b) (4) (b) (4)	05 Nov 2020 20:52:31

US3432260

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Nov 2020 20:52:31

US3432260

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 20:52:31

US3432260

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	05 Nov 2020 20:52:31

US3432260

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User entered empty.	(b) (4), (b) (6) Monica Feeley (b) (4) (b) (4)	13 Nov 2020 16:50:59 05 Nov 2020 20:52:31

US3432260

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Nov 2020 20:52:31

US3432260

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 20:52:31

US3432260

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	Monica Feeley (b) (4) (b) (4)	05 Nov 2020 20:52:31

US3432260

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	05 Nov 2020 20:52:31

US3432260

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Nov 2020 20:52:31

US3432260

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Nov 2020 20:52:31

US3432260

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 13:46:55
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'not discharged yet' (Site from System).	Monica Feeley (b) (4)	05 Nov 2020 20:52:45
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	05 Nov 2020 20:52:31
User entered '1'	Monica Feeley (b) (4)	05 Nov 2020 20:52:31

US3432260

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '04 Nov 2020'	Monica Feeley (b) (4) (b) (4)	05 Nov 2020 20:52:31

US3432260

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Nov 2020 20:52:31

US3432260

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	05 Nov 2020 20:52:31

US3432260

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Nov 2020 20:52:31

US3432260

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Nov 2020 20:52:31

US3432260

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Nov 2020 20:52:31

US3432260

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Nov 2020 20:52:31

US3432260

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Monica Feeley (b) (4) (b) (4)	05 Nov 2020 20:52:31

US3432260

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Monica Feeley (b) (4) (b) (4)	05 Nov 2020 20:52:31

US3432260

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Monica Feeley (b) (4) (b) (4)	05 Nov 2020 20:52:31

US3432260

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

[None](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	05 Nov 2020 20:52:31

US3432260

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Monica Feeley (b) (4) (b) (4)	05 Nov 2020 20:52:31

US3432260

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '1'	Monica Feeley (b) (4) (b) (4)	05 Nov 2020 20:52:31

US3432260

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:51:22
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Monica Feeley (b) (4)	05 Nov 2020 20:52:31

US3432260

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	05 Nov 2020 20:52:31

US3432260

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:52:07
User opened query 'PV Query: Was any other treatment beside surgery given to the subject?. If so, please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no additional treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:52:00
User entered 'has pre-exisiting condition cervical compression and spondylolisthesis. underwent a planned scheduled proceudre 04NOV2020 for cervical fusion C5-C6 with bone graft and hardware placement. Pt is tentatively scheduled for discharge tomorrow 05NOV2020.'	Monica Feeley (b) (4)	05 Nov 2020 20:52:31

US3432260

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 20:52:31

US3432260

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Nov 2020 20:52:31

US3432260

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:23:31

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Nov 2020 20:52:31

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:23:31

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 18:41:36

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: IMMUNOSUPPRESSANTS, ATC: IMMUNOSUPPRESSANTS, ATC: INTERLEUKIN INHIBITORS, PRODUCT: SECUKINUMAB - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 06:44:32
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Oct 2020 06:44:32
Data point term sent to Coder	System	13 Oct 2020 19:49:26
Coding entries removed.	Phoebe Cunningham (b) (4)	13 Oct 2020 19:48:50
User entered 'SECUKINUMAb' reason for change: Data Entry Error	Phoebe Cunningham (b) (4)	13 Oct 2020 19:48:50
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: IMMUNOSUPPRESSANTS, ATC: IMMUNOSUPPRESSANTS, ATC: INTERLEUKIN INHIBITORS, PRODUCT: SECUKINUMAB - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 06:50:48
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 06:50:48
Data point term sent to Coder	System	24 Aug 2020 21:54:10
User entered 'Secukinumab'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 21:54:01

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 21:54:01

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:31

[Indication](#)

Audit	User	Time (GMT)
User entered 'Spondyloarthritis'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 21:54:01

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:31

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '150'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 21:54:01

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:31

[Dose unit](#)

Audit	User	Time (GMT)
Un-reviewed for Data Management.	(b) (4), (b) (6)	12 Nov 2020 18:51:26
Reviewed for Data Management.	(b) (4), (b) (6)	12 Nov 2020 18:51:20
User entered 'mg (mg)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 21:54:01

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 21:54:01

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:31

[Frequency](#)

Audit	User	Time (GMT)
User entered 'other (OTHER)' reason for change: New Information	Phoebe Cunningham (b) (4)	13 Oct 2020 19:48:50
User entered 'every month (QM)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 21:54:01

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 18:51:10
User entered 'five times a week' reason for change: Data Entry Error	Phoebe Cunningham (b) (4)	13 Oct 2020 19:48:50
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 21:54:01

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:31

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Subcutaneous (SUBCUTANEOUS)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 21:54:01

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 21:54:01

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'UN UNK 2018'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 21:54:01

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 21:54:01

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:31

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 21:54:01

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '4 Feb 2020'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 21:54:01

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 21:54:01

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 19:48:50
User entered '1'	System	24 Aug 2020 21:54:01

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 19:48:50
User entered '1'	System	24 Aug 2020 21:54:01

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:23:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 19:48:50
User entered '802 (802)'	System	24 Aug 2020 21:54:01

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, ATC: OTHER MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 00:40:45
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 00:40:45
Data point term sent to Coder	System	24 Aug 2020 22:01:21
User entered 'Botox injection'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:00:32

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:00:32

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:31

[Indication](#)

Audit	User	Time (GMT)
User entered 'Cervical compression'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:00:32

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:31

[Dose per administration](#)

Audit	User	Time (GMT)
User entered 'UNK'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:00:32

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:31

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:00:32

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered 'Unknown'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:00:32

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:31

[Frequency](#)

Audit	User	Time (GMT)
User entered 'other (OTHER)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:00:32

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered 'every 3 months'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:00:32

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:31

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Subcutaneous (SUBCUTANEOUS)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:00:32

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:00:32

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'UN Jun 2020'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:00:32

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:00:32

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:31

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:00:32

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:00:32

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:00:32

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 22:00:32

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 22:00:32

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:23:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 22:00:32

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 08:09:46
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 08:09:46
Data point term sent to Coder	System	24 Aug 2020 22:01:21
User entered 'Gabapentin'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:01:20

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:01:20

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:31

[Indication](#)

Audit	User	Time (GMT)
User entered 'Pain related to spondyloarthritis'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:01:20

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:31

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:01:20

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:31

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:01:20

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:01:20

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:31

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:01:20

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:01:20

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:31

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:01:20

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:01:20

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'UN UNK 2019'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:01:20

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:01:20

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:31

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:01:20

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:01:20

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:01:20

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 22:01:20

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 22:01:20

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:23:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 22:01:20

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 07:41:43
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Aug 2020 07:41:43
Data point term sent to Coder	System	24 Aug 2020 22:02:23
User entered 'Ibuprofen'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:02:05

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:02:05

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:31

[Indication](#)

Audit	User	Time (GMT)
User entered 'Pain related to Spondyloarthritis'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:02:05

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:31

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '400'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:02:05

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:31

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:02:05

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:02:05

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:31

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:02:05

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:02:05

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:31

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:02:05

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:02:05

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:02:05

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:02:05

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:31

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:02:05

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:02:05

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:02:05

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 22:02:05

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 22:02:05

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:23:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 22:02:05

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Aug 2020 22:05:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Aug 2020 22:05:08
Data point term sent to Coder	System	24 Aug 2020 22:03:26
User entered 'Acetaminophen'	Julia Klopfer (b) (4)	24 Aug 2020 22:03:00
	(b) (4)	

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:03:00

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:31

[Indication](#)

Audit	User	Time (GMT)
User entered 'Pain related to spondyloarthritis'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:03:00

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:31

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '500'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:03:00

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:31

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:03:00

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:03:00

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:31

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:03:00

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:03:00

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:31

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:03:00

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:03:00

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'UN UNK 2015'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:03:00

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:03:00

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:31

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:03:00

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:03:00

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:03:00

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 22:03:00

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 22:03:00

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:23:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 22:03:00

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: ESOMEPRAZOLE MAGNESIUM, PRODUCTSYNONYM: NEXIUM [ESOMEPRAZOLE MAGNESIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 19:15:56
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 19:15:56
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: ESOMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 22:05:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Aug 2020 22:05:10
Data point term sent to Coder	System	24 Aug 2020 22:04:29
User entered 'Nexium'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:03:39

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:03:39

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:31

[Indication](#)

Audit	User	Time (GMT)
User entered 'GERD'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:03:39

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:31

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:03:39

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:31

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:03:39

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:03:39

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:31

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:03:39

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:03:39

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:31

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:03:39

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:03:39

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered 'UN UNK 2017'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:03:39

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:03:39

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:31

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:03:39

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:03:39

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	24 Aug 2020 22:03:39

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 22:03:39

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Aug 2020 22:03:39

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:23:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 22:03:39

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: MOTRIN [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 21:35:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 21:35:30
Data point term sent to Coder	System	01 Sep 2020 21:34:03
User entered 'Motrin'	Phoebe Cunningham (b) (4)	01 Sep 2020 21:33:57

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Phoebe Cunningham (b) (4)	01 Sep 2020 21:33:57

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:31

[Indication](#)

Audit	User	Time (GMT)
User entered 'Headache'	Phoebe Cunningham	01 Sep 2020 21:33:57
	(b) (4)	

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:31

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please provide the actual dose administered (either 600 or 800) instead of the dose range in this field. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 06:31:57
Comment added 'updated to 800mg'.	Bruce Bausk (b) (4)	19 Oct 2020 20:40:31
User entered '800' reason for change: Data Entry Error	(b) (4)	
Query 'Per DM CLR: Please provide the actual dose administered (either 600 or 800) instead of the dose range in this field.	Bruce Bausk (b) (4)	19 Oct 2020 20:40:21
' answered with 'dose varies as needed' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please provide the actual dose administered (either 600 or 800) instead of the dose range in this field.	Bruce Bausk (b) (4)	19 Oct 2020 20:38:49
' answered with 'dose varies as needed' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please provide the actual dose administered (either 600 or 800) instead of the dose range in this field. ' (Site from DM).	(b) (4), (b) (6)	03 Oct 2020 06:20:16
User entered '600-800'	Phoebe Cunningham (b) (4)	01 Sep 2020 21:33:57

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:31

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Phoebe Cunningham	01 Sep 2020 21:33:57
	(b) (4)	

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	01 Sep 2020 21:33:57

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:31

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once (ONCE)'	Phoebe Cunningham (b) (4)	01 Sep 2020 21:33:57

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	01 Sep 2020 21:33:57

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:31

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Phoebe Cunningham (b) (4)	01 Sep 2020 21:33:57

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	01 Sep 2020 21:33:57

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '27 Aug 2020'	Phoebe Cunningham (b) (4)	01 Sep 2020 21:33:57

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Phoebe Cunningham (b) (4)	01 Sep 2020 21:33:57

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:31

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Phoebe Cunningham (b) (4)	01 Sep 2020 21:33:57

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '27 Aug 2020'	Phoebe Cunningham (b) (4)	01 Sep 2020 21:33:57

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	01 Sep 2020 21:33:57

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 21:33:57

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 21:33:57

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:23:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Sep 2020 21:33:57

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANATE POTASSIUM, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN;CLAVULANATE POTASSIUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 03:56:58
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 03:56:58
Data point term sent to Coder	System	16 Nov 2020 19:19:11
Coding entries removed.	(b) (4), (b) (6)	16 Nov 2020 19:18:29
User entered 'AUGMENTIN (amoxicillin/clavulanate)' reason for change: Per Query Resolution	(b) (4), (b) (6)	16 Nov 2020 19:18:29
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN;CLAVULANIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 23:13:45
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 23:13:45
Data point term sent to Coder	System	21 Sep 2020 21:47:00
Coding entries removed.	(b) (4), (b) (6)	21 Sep 2020 21:46:06
User entered 'AUGMENTIN' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 21:46:06

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: AMOXICILLIN;CLAVULANIC ACID, PRODUCTSYNONYM: AUGMENTIN [AMOXICILLIN;CLAVULANIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 01:04:46
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 01:04:46
Data point term sent to Coder	System	11 Sep 2020 00:04:25
User entered 'Agmentin'	Xhoi Mitre (b) (4) (b) (4)	11 Sep 2020 00:03:29

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	11 Sep 2020 00:03:29

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:31

[Indication](#)

Audit	User	Time (GMT)
User entered 'Sinusitis'	Xhoi Mitre (b) (4) (b) (4)	11 Sep 2020 00:03:29

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:31

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 08:02:14
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' answered with 'Dose field has been updated' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 19:18:44
User entered '875/125' reason for change: Per Query Resolution	(b) (4), (b) (6)	16 Nov 2020 19:17:54
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 15:29:41
User entered '875'	Xhoi Mitre (b) (4) (b) (4)	11 Sep 2020 00:03:29

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:31

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Xhoi Mitre (b) (4) (b) (4)	11 Sep 2020 00:03:29

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	11 Sep 2020 00:03:29

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:31

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Xhoi Mitre (b) (4) (b) (4)	11 Sep 2020 00:03:29

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	11 Sep 2020 00:03:29

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:31

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Xhoi Mitre (b) (4) (b) (4)	11 Sep 2020 00:03:29

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	11 Sep 2020 00:03:29

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '04 Sep 2020'	Xhoi Mitre (b) (4) (b) (4)	11 Sep 2020 00:03:29

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	11 Sep 2020 00:03:29

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:31

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 08:02:30
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'pt has been contacted and reports that end date was sometime in September, pt does not remember when' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 19:20:23
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	16 Nov 2020 19:19:32
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 15:31:07
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	11 Sep 2020 00:03:29

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'End date is prior to start date. Please correct.' (Site from System).	System	16 Nov 2020 19:19:32
User entered 'un Sep 2020' reason for change: New Information	(b) (4), (b) (6)	16 Nov 2020 19:19:32
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	11 Sep 2020 00:03:37
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	11 Sep 2020 00:03:37
User entered empty; reason for change Data Entry Error	Xhoi Mitre (b) (4)	11 Sep 2020 00:03:37
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	11 Sep 2020 00:03:29
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	11 Sep 2020 00:03:29
User entered '11 Sep 2020'	Xhoi Mitre (b) (4)	11 Sep 2020 00:03:29

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	11 Sep 2020 00:03:29

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	11 Sep 2020 00:03:29

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 00:03:29

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:23:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 00:03:29

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 19:20:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Nov 2020 19:20:48
Data point term sent to Coder	System	13 Nov 2020 19:19:51
Coding entries removed.	(b) (4), (b) (6)	13 Nov 2020 19:19:22
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE PROPIONATE, PRODUCTSYNONYM: FLONASE [FLUTICASONE PROPIONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 22:37:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 22:37:48
Data point term sent to Coder	System	21 Sep 2020 22:37:27
User entered 'Flonase'	Jessica Cauley (b) (4) (b) (4)	21 Sep 2020 22:36:53

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Cauley (b) (4) (b) (4)	21 Sep 2020 22:36:53

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:31

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of ALLERGIES (seasonal, medication, food, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 08:03:08
Query 'Per DM CLR: Please update the indication to reflect the location and type of ALLERGIES (seasonal, medication, food, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'Has been resolved to match MH' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 19:19:33
User entered 'Seasonal ALLERGIES' reason for change: Per Query Resolution	(b) (4), (b) (6)	13 Nov 2020 19:19:22
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of ALLERGIES (seasonal, medication, food, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 15:34:41
User entered 'allergies'	Jessica Cauley (b) (4) (b) (4)	21 Sep 2020 22:36:53

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:31

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '2'	Jessica Cauley (b) (4) (b) (4)	21 Sep 2020 22:36:53

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:31

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	Jessica Cauley (b) (4) (b) (4)	21 Sep 2020 22:36:53

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered 'sprays each nostril'	Jessica Cauley (b) (4) (b) (4)	21 Sep 2020 22:36:53

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:31

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Jessica Cauley (b) (4) (b) (4)	21 Sep 2020 22:36:53

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Cauley (b) (4) (b) (4)	21 Sep 2020 22:36:53

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:31

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Nasal (NASAL)'	Jessica Cauley (b) (4) (b) (4)	21 Sep 2020 22:36:53

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jessica Cauley (b) (4) (b) (4)	21 Sep 2020 22:36:53

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '2 Sep 2020'	Jessica Cauley (b) (4) (b) (4)	21 Sep 2020 22:36:53

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Cauley (b) (4) (b) (4)	21 Sep 2020 22:36:53

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:31

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Cauley (b) (4) (b) (4)	21 Sep 2020 22:36:53

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '3 Sep 2020'	Jessica Cauley (b) (4) (b) (4)	21 Sep 2020 22:36:53

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Cauley (b) (4) (b) (4)	21 Sep 2020 22:36:53

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 22:36:53

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 22:36:53

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:23:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 22:36:53

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 19:20:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Nov 2020 19:20:49
Data point term sent to Coder	System	13 Nov 2020 19:19:51
Coding entries removed.	(b) (4), (b) (6)	13 Nov 2020 19:19:48
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE, PRODUCTSYNONYM: CLARITIN [LORATADINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 22:39:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Sep 2020 22:39:49
Data point term sent to Coder	System	21 Sep 2020 22:38:29
User entered 'Claritin'	Jessica Cauley (b) (4)	21 Sep 2020 22:37:38

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Cauley (b) (4) (b) (4)	21 Sep 2020 22:37:38

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:31

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please update the indication to reflect the location and type of ALLERGIES (seasonal, medication, food, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 08:03:19
Query 'Per DM CLR: Please update the indication to reflect the location and type of ALLERGIES (seasonal, medication, food, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' answered with 'has been updated to match MH' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 19:19:59
User entered 'seasonal ALLERGIES' reason for change: Per Query Resolution	(b) (4), (b) (6)	13 Nov 2020 19:19:48
User opened query 'Per DM CLR: Please update the indication to reflect the location and type of ALLERGIES (seasonal, medication, food, etc.). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 15:35:29
User entered 'allergies'	Jessica Cauley (b) (4) (b) (4)	21 Sep 2020 22:37:38

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:31

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	Jessica Cauley (b) (4) (b) (4)	21 Sep 2020 22:37:38

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:31

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Jessica Cauley (b) (4) (b) (4)	21 Sep 2020 22:37:38

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jessica Cauley (b) (4) (b) (4)	21 Sep 2020 22:37:38

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:31

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Jessica Cauley (b) (4) (b) (4)	21 Sep 2020 22:37:38

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Cauley (b) (4) (b) (4)	21 Sep 2020 22:37:38

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:31

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Jessica Cauley (b) (4) (b) (4)	21 Sep 2020 22:37:38

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Jessica Cauley (b) (4) (b) (4)	21 Sep 2020 22:37:38

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '2 Sep 2020'	Jessica Cauley (b) (4) (b) (4)	21 Sep 2020 22:37:38

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Jessica Cauley (b) (4) (b) (4)	21 Sep 2020 22:37:38

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:31

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Cauley (b) (4) (b) (4)	21 Sep 2020 22:37:38

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '3 Sep 2020'	Jessica Cauley (b) (4) (b) (4)	21 Sep 2020 22:37:38

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Cauley (b) (4) (b) (4)	21 Sep 2020 22:37:38

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 22:37:38

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 22:37:38

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:23:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Sep 2020 22:37:38

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 21:31:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Sep 2020 21:31:15
Data point term sent to Coder	System	28 Sep 2020 21:30:10
User entered 'ibuprofen'	Phoebe Cunningham (b) (4)	28 Sep 2020 21:29:41

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Sep 2020 21:29:41

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:31

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '800'	Phoebe Cunningham	28 Sep 2020 21:29:41
	(b) (4)	

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:31

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Phoebe Cunningham	28 Sep 2020 21:29:41
	(b) (4)	

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	28 Sep 2020 21:29:41

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:31

[Frequency](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review frequency as this was not given once per ongoing dates. Either update frequency or provide end date. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 18:49:37
User entered 'once (ONCE)'	Phoebe Cunningham (b) (4)	28 Sep 2020 21:29:41

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	28 Sep 2020 21:29:41

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:31

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Phoebe Cunningham (b) (4)	28 Sep 2020 21:29:41

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	28 Sep 2020 21:29:41

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '25 Sep 2020'	Phoebe Cunningham (b) (4)	28 Sep 2020 21:29:41

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Phoebe Cunningham (b) (4)	28 Sep 2020 21:29:41

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:31

[Ongoing?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please confirm if this medication is still ongoing as the noted solicited adverse reaction has already resolved in the Diary card. Reconcile and update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 18:50:06
User entered 'Yes (Y)' reason for change: Data Entry Error	Phoebe Cunningham (b) (4)	05 Oct 2020 20:55:03
User entered 'No (N)'	Phoebe Cunningham (b) (4)	28 Sep 2020 21:29:41

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty; reason for change Data Entry Error	Phoebe Cunningham (b) (4)	05 Oct 2020 20:55:03
User entered '25 Sep 2020'	Phoebe Cunningham (b) (4)	28 Sep 2020 21:29:41

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	28 Sep 2020 21:29:41

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 21:29:41

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 21:29:41

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:23:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	28 Sep 2020 21:29:41

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: IMMUNOSUPPRESSANTS, ATC: IMMUNOSUPPRESSANTS, ATC: INTERLEUKIN INHIBITORS, PRODUCT: SECUKINUMAB, PRODUCTSYNONYM: COSENTYX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Oct 2020 15:44:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Oct 2020 15:44:33
Data point term sent to Coder	System	24 Oct 2020 15:43:45
User entered 'cosentyx'	(b) (4), (b) (6)	24 Oct 2020 15:42:52

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	24 Oct 2020 15:42:52

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:31

[Indication](#)

Audit	User	Time (GMT)
User entered 'arthritis'	(b) (4), (b) (6)	24 Oct 2020 15:42:52

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:31

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '150'	(b) (4), (b) (6)	24 Oct 2020 15:42:52

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:31

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	24 Oct 2020 15:42:52

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Oct 2020 15:42:52

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:31

[Frequency](#)

Audit	User	Time (GMT)
User entered 'other (OTHER)'	(b) (4), (b) (6)	24 Oct 2020 15:42:52

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered 'weekly for 5 weeks and then monthly'	(b) (4), (b) (6)	24 Oct 2020 15:42:52

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:31

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	24 Oct 2020 15:42:52

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Oct 2020 15:42:52

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '7 Oct 2020'	(b) (4), (b) (6)	24 Oct 2020 15:42:52

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Oct 2020 15:42:52

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:31

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Oct 2020 15:42:52

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Oct 2020 15:42:52

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	24 Oct 2020 15:42:52

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Oct 2020 15:42:52

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Oct 2020 15:42:52

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:23:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Oct 2020 15:42:52

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:31

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Oct 2020 15:45:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Oct 2020 15:45:34
Data point term sent to Coder	System	24 Oct 2020 15:44:46
User entered 'prednisone'	(b) (4), (b) (6)	24 Oct 2020 15:43:56

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	24 Oct 2020 15:43:56

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:31

[Indication](#)

Audit	User	Time (GMT)
User entered 'arthritis'	(b) (4), (b) (6)	24 Oct 2020 15:43:56

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:31

[Dose per administration](#)

Audit	User	Time (GMT)
User entered 'taper'	(b) (4), (b) (6)	24 Oct 2020 15:43:56

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:31

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'Other (OTHER)'	(b) (4), (b) (6)	24 Oct 2020 15:43:56

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:31

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	24 Oct 2020 15:44:03
User entered 'taper' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Oct 2020 15:44:03
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	24 Oct 2020 15:43:56
User entered empty.	(b) (4), (b) (6)	24 Oct 2020 15:43:56

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:31

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	(b) (4), (b) (6)	24 Oct 2020 15:43:56

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Oct 2020 15:43:56

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:31

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	24 Oct 2020 15:43:56

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Oct 2020 15:43:56

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:31

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

Audit	User	Time (GMT)
User entered '10 Oct 2020'	(b) (4), (b) (6)	24 Oct 2020 15:43:56

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	24 Oct 2020 15:43:56

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:31

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	24 Oct 2020 15:43:56

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '15 Oct 2020'	(b) (4), (b) (6)	24 Oct 2020 15:43:56

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	24 Oct 2020 15:43:56

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Oct 2020 15:43:56

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Oct 2020 15:43:56

US3432260

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:23:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Oct 2020 15:43:56

US3432260

Folder: SAE USA-US078-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:31

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:03:36
User entered 'USA-US078-2020-MRNA-1273-P301000010'	System	06 Nov 2020 19:03:12

US3432260

Folder: SAE USA-US078-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:31

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:03:36
User entered 'Yes (Y)'	System	06 Nov 2020 19:03:12

US3432260

Folder: SAE USA-US078-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:31

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:03:36
User entered 'No (N)'	System	06 Nov 2020 19:03:12

US3432260

Folder: SAE USA-US078-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:31

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:03:36
User entered 'No (N)'	System	06 Nov 2020 19:03:12

US3432260

Folder: SAE USA-US078-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:03:36
User entered 'Yes (Y)'	System	06 Nov 2020 19:03:12

US3432260

Folder: SAE USA-US078-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:03:36
User entered 'No (N)'	System	06 Nov 2020 19:03:12

US3432260

Folder: SAE USA-US078-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:03:36
User entered 'No (N)'	System	06 Nov 2020 19:03:12

US3432260

Folder: SAE USA-US078-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:31

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:03:36
User entered 'No (N)'	System	06 Nov 2020 19:03:12

US3432260

Folder: SAE USA-US078-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:03:36
User entered 'Lindsey'	System	06 Nov 2020 19:03:12

US3432260

Folder: SAE USA-US078-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:03:36
User entered 'Baden'	System	06 Nov 2020 19:03:12

US3432260

Folder: SAE USA-US078-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:31

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:03:36
User entered 'MA'	System	06 Nov 2020 19:03:12

US3432260

Folder: SAE USA-US078-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:31

[Investigator Country](#)

Audit	User	Time (GMT)
User entered 'US'	System	06 Nov 2020 19:03:42

US3432260

Folder: SAE USA-US078-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 19:03:42

US3432260

Folder: SAE USA-US078-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:31

[SAEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:03:36
User entered 'USA-US078-2020-MRNA-1273-P301000010'	System	06 Nov 2020 19:03:12

US3432260

Folder: SAE USA-US078-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:31

Serious

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:03:36
User entered 'Yes (Y)'	System	06 Nov 2020 19:03:12

US3432260

Folder: SAE USA-US078-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:31

[Death](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:03:36
User entered 'No (N)'	System	06 Nov 2020 19:03:12

US3432260

Folder: SAE USA-US078-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:31

[Life threatening](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:03:36
User entered 'No (N)'	System	06 Nov 2020 19:03:12

US3432260

Folder: SAE USA-US078-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:03:36
User entered 'Yes (Y)'	System	06 Nov 2020 19:03:12

US3432260

Folder: SAE USA-US078-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:03:36
User entered 'No (N)'	System	06 Nov 2020 19:03:12

US3432260

Folder: SAE USA-US078-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:03:36
User entered 'No (N)'	System	06 Nov 2020 19:03:12

US3432260

Folder: SAE USA-US078-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:31

[Other medically important event](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:03:36
User entered 'No (N)'	System	06 Nov 2020 19:03:12

US3432260

Folder: SAE USA-US078-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:03:36
User entered 'Lindsey'	System	06 Nov 2020 19:03:12

US3432260

Folder: SAE USA-US078-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:03:36
User entered 'Baden'	System	06 Nov 2020 19:03:12

US3432260

Folder: SAE USA-US078-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:31

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 19:03:36
User entered 'MA'	System	06 Nov 2020 19:03:12

US3432260

Folder: SAE USA-US078-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:31

[Investigator Country](#)

Audit	User	Time (GMT)
User entered 'US'	System	06 Nov 2020 19:03:42

US3432260

Folder: SAE USA-US078-2020-MRNA-1273-P301000010

Form: Safety Report Form

Generated On: 26 Nov 2020 09:23:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Nov 2020 19:03:42

US3432260

Folder: SAE USA-US078-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:23:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '06/Nov/2020 19:03'	System	06 Nov 2020 19:03:42

US3432260

Folder: SAE USA-US078-2020-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:23:31

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	06 Nov 2020 19:03:42