

US3432208 (Prod: Brigham and Womens Hospital)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:27:55

All time stamps listed in this document are displayed in GMT

US3432208

Form: Participant Creation

Generated On: 26 Nov 2020 09:27:55

[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 09:27:55

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	20 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 09:27:55

Date of Birth (MMM yyyy)	(b) (6) 1965
Age	54
Age Units	YEARS
Age (Derived)	54
Sex	Female ☐ Male ☒
Ethnicity	Hispanic or Latino ☒ Not Hispanic or Latino ☐ Not Reported ☐ Unknown ☐
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:27:55

Date of Informed Consent (<i>dd MMM yyyy</i>)	20 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 09:27:55

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:27:55

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:27:55

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

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:27:55

Condition	TYPE II DIABETES
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 (3)

Generated On: 26 Nov 2020 09:27:55

Condition	DEPRESSION
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 (4)

Generated On: 26 Nov 2020 09:27:55

Condition	DYSPEPSIA
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 (5)

Generated On: 26 Nov 2020 09:27:55

Condition	BARIATRIC SURGERY
Start date (dd MMM yyyy)	31 OCT 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	31 OCT 2019
Stop date completely unknown	False
Start Month and Year (derived)	OCT 2019
Start Year (derived)	2019
Stop Month and Year (derived)	OCT 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:27:55

Condition	SPINE CORRECTIVE SURGERY
Start date (dd MMM yyyy)	17 JUN 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	17 JUN 2019
Stop date completely unknown	False
Start Month and Year (derived)	JUN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JUN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:27:55

Condition	CLINDAMYCIN ALLERGY (RASH)
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 (8)

Generated On: 26 Nov 2020 09:27:55

Condition	CIPROFLOX (RASH)
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: Vital Signs

Generated On: 26 Nov 2020 09:27:55

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	20 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	9:40 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 9:40
Height (<i>xxx.x</i>)	161.6 cm
Weight (<i>xxx.x</i>)	78.5 kg
BMI (<i>xxx.x</i>)	30.05986 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 09:27:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 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: Risk of Exposure

Generated On: 26 Nov 2020 09:27:55

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 09:27:55

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	20 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 09:27:55

What was the date of randomization? (dd MMM yyyy) 20 AUG 2020

What was the participant's randomization number? 144051

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 09:27:55

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 09:27:55

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)	20 AUG 2020
Time of assessment (00:00-23:59)	9:40 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 9:40
Temperature (xxx.x)	36.4 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	53 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 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 09:27:55

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)	20 AUG 2020
Time of assessment (00:00-23:59)	12:16 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 12:16
Temperature (xxx.x)	36.3 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	51 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:27:55

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 09:27:55

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)	20 AUG 2020
What was the treatment time? (00:00-23:59)	11:45 (24 HR)
Treatment Date and Time (derived)	20 AUG 2020 11:45
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 09:27:55

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

20 AUG 2020

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

10:29 (24 HR)

Collection date and time (derived)

20 AUG 2020 10:29

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:27:55

Collection date (<i>dd MMM yyyy</i>)			20 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	10:16	20 AUG 2020 10:16
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:27:55

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 09:27:55

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

20 AUG 2020 12:22

PC Open Date & Time

20 AUG 2020 12:05

PC Close Date & Time

20 AUG 2020 14:35

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.7 °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	20 AUG 2020 17:26
PC Open Date & Time	20 AUG 2020 15:30
PC Close Date & Time	21 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:27:55

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

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 12:12

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °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

23 AUG 2020 08:18

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:27:55

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 11:11

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:27:55

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

97.7 °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

25 AUG 2020 07:59

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °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 AUG 2020 07:51

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

27 AUG 2020 07:34

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

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

20 AUG 2020 12:23

PC Open Date & Time

20 AUG 2020 12:05

PC Close Date & Time

20 AUG 2020 14:35

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

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

20 AUG 2020 17:26

PC Open Date & Time

20 AUG 2020 15:30

PC Close Date & Time

21 AUG 2020 11:59

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:27:55

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

21 AUG 2020 12:13

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:27:55

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

23 AUG 2020 08:19

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 11:11

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 07:59

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:27:55

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 AUG 2020 07:51

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

27 AUG 2020 07:34

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 12:24
PC Open Date & Time	20 AUG 2020 12:05
PC Close Date & Time	20 AUG 2020 14:35

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 17:27
PC Open Date & Time	20 AUG 2020 15:30
PC Close Date & Time	21 AUG 2020 11:59

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:55

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 ☒

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:55

Yes ☐	
PC Time stamp	21 AUG 2020 12:14
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:55

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 ☒

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:55

Yes ☐	
PC Time stamp	23 AUG 2020 08:19
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:55

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 ☒

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:55

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

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:55

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 ☒

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:55

Yes ☐	
PC Time stamp	25 AUG 2020 08:00
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:55

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 ☒

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:55

Yes ☐	
PC Time stamp	26 AUG 2020 07:51
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:55

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 ☒

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:55

Yes ☐	
PC Time stamp	27 AUG 2020 07:34
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3432208

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:55

Was Contact Attempted?

Yes ☒

No ☐

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

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432208

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432208

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:55

Was Contact Attempted?

Yes ☒

No ☐

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

03 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432208

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432208

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432208

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432208

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:27:55

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	17 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:55

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	17 SEP 2020
Time of assessment (00:00-23:59)	8:26 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 8:26
Temperature (xxx.x)	36.8 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:55

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	17 SEP 2020
Time of assessment (00:00-23:59)	10:19 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 10:19
Temperature (xxx.x)	37.0 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	93 mmHg
Diastolic Blood Pressure units	MMHG

US3432208

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:27:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 SEP 2020

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

US3432208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:27:55

Was study treatment given?	Yes ☒
	No ☐
If No, reason not given	Participant declined due to Adverse Event ☐
	Physician withheld dose due to Adverse Event ☐
	Death ☐
	Lost To Follow-Up ☐
	Physician Decision ☐
	Pregnancy ☐
	Protocol Deviation ☐
	Study Terminated by Sponsor ☐
	Withdrawal of Consent by Participant ☐
	Confirmed COVID-19 ☐
	Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	17 SEP 2020
What was the treatment time? (00:00-23:59)	09:49 (24 HR)
Treatment Date and Time (derived)	17 SEP 2020 09:49
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

US3432208

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:27:55

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	17 SEP 2020
Collection time (<i>00:00-23:59</i>)	09:30 (24 HR)
Collection date and time (derived)	17 SEP 2020 09:30

US3432208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:27:55

Collection date (dd MMM yyyy)			17 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:35	17 SEP 2020 09:35
Nasopharyngeal Swab 2	No		

US3432208

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐
No ☒

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

PC Time Stamp 17 SEP 2020 10:26

PC Open Date & Time 17 SEP 2020 10:09

PC Close Date & Time 17 SEP 2020 12:39

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.5 °F

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

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

PC Time Stamp	18 SEP 2020 09:50
PC Open Date & Time	17 SEP 2020 13:34
PC Close Date & Time	18 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

19 SEP 2020 11:21

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:27:55

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 08:32

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 22:36

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:27:55

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 13:17

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 08:05

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:27:55

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 10:22

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

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

17 SEP 2020 10:26

PC Open Date & Time

17 SEP 2020 10:09

PC Close Date & Time

17 SEP 2020 12:39

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 09:51

PC Open Date & Time

17 SEP 2020 13:34

PC Close Date & Time

18 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 11:21

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 08:32

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 22:37

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 13:17

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 08:05

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 10:22

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 10:27
PC Open Date & Time	17 SEP 2020 10:09
PC Close Date & Time	17 SEP 2020 12:39

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

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

No ☒

Yes ☐

PC Time stamp	18 SEP 2020 09:51
PC Open Date & Time	17 SEP 2020 13:34
PC Close Date & Time	18 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:55

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 ☒

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:55

Yes ☐	
PC Time stamp	19 SEP 2020 11:22
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:55

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 ☒

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:55

Yes ☐	
PC Time stamp	20 SEP 2020 08:33
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:55

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 ☒

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:55

Yes ☐	
PC Time stamp	20 SEP 2020 22:37
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:55

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 ☒

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:55

Yes ☐	
PC Time stamp	21 SEP 2020 13:18
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:55

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 ☒

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:55

Yes ☐	
PC Time stamp	23 SEP 2020 08:05
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:55

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 ☒

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:55

Yes ☐	
PC Time stamp	24 SEP 2020 10:23
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3432208

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:55

Was Contact Attempted?

Yes ☒

No ☐

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

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432208

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432208

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432208

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432208

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432208

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432208

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:27:55

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	13 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3432208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:55

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	13 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	8:22 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 8:22
Temperature (<i>xxx.x</i>)	98.4 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	97 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432208

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:27:55

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 OCT 2020

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

US3432208

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:27:55

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	13 OCT 2020
Collection time (<i>00:00-23:59</i>)	8:56 (24 HR)
Collection date and time (derived)	13 OCT 2020 8:56

US3432208

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 OCT 2020 06:55:05
Patient Cloud Open Date & Time	27 OCT 2020 00:01
Patient Cloud Close Date & Time	31 OCT 2020 23:59

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 NOV 2020 00:02:15

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

21 OCT 2020 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

28 OCT 2020 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2020 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2020 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

18 NOV 2020 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 NOV 2020 13:19:07
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2020 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2020 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

Date and time of submission	
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2020 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

30 DEC 2020 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2021 00:01

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10 FEB 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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17 FEB 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

Please contact your study clinic immediately. Click below to confirm that you have read this 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 FEB 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

Please contact your study clinic immediately. Click below to confirm that you have read this 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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27 FEB 2021 00:01

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03 MAR 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAR 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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24 MAR 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAR 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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07 APR 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2021 00:01

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14 APR 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

28 APR 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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°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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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°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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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06 APR 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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25 MAY 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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08 JUN 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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15 JUN 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

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22 JUN 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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29 JUN 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

Please contact your study clinic immediately. Click below to confirm that you have read this 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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02 JUL 2022 00:01

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06 JUL 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

Please contact your study clinic immediately. Click below to confirm that you have read this 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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09 JUL 2022 00:01

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13 JUL 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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20 JUL 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

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27 JUL 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

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03 AUG 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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

Date and time of submission

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06 AUG 2022 00:01

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10 AUG 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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17 AUG 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

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24 AUG 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01
Patient Cloud Close Date & Time	19 OCT 2022 23:59

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

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

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3432208

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:55

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432208

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:55

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432208

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:55

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

US3432208

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:55

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3432208

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:27:55

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
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 ☐

US3432208

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:27:55

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3432208

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:27:55

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

AEID	USA-US078-2020-MRNA-1273-P30 1000004
Adverse event	SPINAL STENOSIS
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)	07 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ☒
If not Ongoing, end date (dd MMM yyyy)	05 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ☒ Grade 4 ☐
Is the adverse event serious?	Yes ☒ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	02 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	05 OCT 2020
Admitted to ICU?	Yes ☐ No ☒ Unknown ☐
Number of Days in ICU	

v6.020 DTW (1102) 338 of 1917

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

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	

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

AN MRI OF C-SPINE ON 9/7/2020
REVEALED CANAL STENOSIS
AT C5-7; HE UNDERWENT AN
ANTERIOR CERVICAL
DISECTOMY + FUSION ON
10/2/2020; POST OP COURSE
UNREMARKABLE AND
DISCHARGED ON 10/5/2020.
PARTICIPANT REPORTED THIS
TO SITE ON 13OCT2020 DURING
THEIR SCHEDULED VISIT 3.

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

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:27:55

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

Yes ☒

No ☐

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

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:55

Name of Medication	NORVASC
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
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 ☐

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:55

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

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:55

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

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:55

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 2018
Start date completely unknown	False	
Ongoing?	Yes	☒
	No	☐
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	☐
	No	☒
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:55

Name of Medication	SERTRALINE
Prophylaxis	Yes ☐ No ☒
Indication	DEPRESSION
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 ☐

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:55

	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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	☐
	803	☐
	804	☒

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:55

Name of Medication	OMEPRAZOLE
Prophylaxis	Yes ☐ No ☒
Indication	DYSPEPSIA
Dose per administration	40
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☒
If frequency is Other, specify	
Route of administration	TWICE A DAY AND AS NEEDED Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:55

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

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:55

Name of Medication	LORAZEPAM
Prophylaxis	Yes ☐ No ☒
Indication	ANXIETY
Dose per administration	0.5
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:55

	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)		5 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		6 OCT 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	☐

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:55

Name of Medication	HYDROMORPHONE
Prophylaxis	Yes ☐ No ☒
Indication	PAIN FROM SPINE SURGERY
Dose per administration	0.2-0.5
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:55

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

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:55

Name of Medication	HYDROMORPHONE
Prophylaxis	Yes ☐ No ☒
Indication	PAIN FROM SPINE SURGERY
Dose per administration	2-4
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☒
If frequency is Other, specify	
Route of administration	EVERY 3 HOURS Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:55

	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)	4 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)	6 OCT 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	☐

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:27:55

Name of Medication	OXYCODONE
Prophylaxis	Yes ☐ No ☒
Indication	PAIN FROM SPINE SURGERY
Dose per administration	5-10
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 ☐

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:27:55

	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 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		4 OCT 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 ☐

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:27:55

Name of Medication	ZOFRAN
Prophylaxis	Yes ☐ No ☒
Indication	NAUSEA
Dose per administration	4
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☒
If frequency is Other, specify	
Route of administration	EVERY 6 HOURS Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:27:55

	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 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		06 OCT 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 ☐

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:27:55

Name of Medication	ZOFRAN
Prophylaxis	Yes ☐ No ☒
Indication	NAUSEA
Dose per administration	2
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☒
If frequency is Other, specify	
Route of administration	EVERY 6 HOURS Oral ☐ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:27:55

	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 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		6 OCT 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 ☐	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:27:55

Name of Medication	ACETAMINOPHEN
Prophylaxis	Yes ☐ No ☒
Indication	PAIN FROM SURGERY FOR SPINAL STENOSIS
Dose per administration	650
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	EVERY 6 HOURS Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:27:55

	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)	2 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		6 OCT 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 ☐	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:27:55

Name of Medication	DULCOLAX
Prophylaxis	Yes ☐ No ☒
Indication	CONSTIPATION
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 ☐

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:27:55

	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 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		6 OCT 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	☐

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:27:55

Name of Medication	COLACE
Prophylaxis	Yes ☐ No ☒
Indication	CONSTIPATION
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 ☐ Intramuscular ☐

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:27:55

	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 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	☐

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:27:55

Name of Medication	HYDROCODONE/ ACETAMINOPHEN
Prophylaxis	Yes ☐ No ☒
Indication	PAIN FROM SURGERY FOR SPINAL STENOSIS
Dose per administration	7.5-325
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 ☐

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:27:55

	Intraocular	☐
	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)	05 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		14 OCT 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	☐

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:27:55

Name of Medication	LIDOCAINE PATCH (4%)
Prophylaxis	Yes ☐ No ☒
Indication	PAIN FROM SURGERY FOR SPINAL STENOSIS
Dose per administration	1
Dose unit	mg ☐ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☒
If dose unit is Other, specify	APPLICATION
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 ☐

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:27:55

	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)	4 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes ☐	
	No ☒	
If not Ongoing, End date (dd MMM yyyy)		06 OCT 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 ☐	

US3432208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:27:55

[Were any concomitant procedures performed?](#)

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3432208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Generated On: 26 Nov 2020 09:27:55

Procedure/Surgery date (<i>dd MMM yyyy</i>)	Procedure/Surgery	Indication	If indication is Other, specify
02 OCT 2020	DISCECTOMY ANTERIOR CERVICAL SPINE FUSION	Adverse Event	
07 SEP 2020	CERVICAL SPINE MRI	Adverse Event	

US3432208

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:27:55

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

US3432208

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:27:55

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 ☐

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

SAEID	USA-US078-2020-MRNA-1273-P301000004
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)	5

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:27:55

SAEID	USA-US078-2020-MRNA-1273-P301000004
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)	5
Date of submission (Pre-filled from custom function)	14/OCT/2020 08:02
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

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:27:55

SAEID	USA-US078-2020-MRNA-1273-P301000004
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)	5
Date of submission (Pre-filled from custom function)	16/OCT/2020 11:08
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

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:27:55

SAEID	USA-US078-2020-MRNA-1273-P301000004
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)	5
Date of submission (Pre-filled from custom function)	
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.	False

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:27:55

SAEID	USA-US078-2020-MRNA-1273-P301000004
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)	5
Date of submission (Pre-filled from custom function)	02/NOV/2020 13:46
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

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:27:55

SAEID	USA-US078-2020-MRNA-1273-P301000004
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)	5
Date of submission (Pre-filled from custom function)	11/NOV/2020 17:58
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 09:27:55

SAEID	USA-US078-2020-MRNA-1273-P301000004
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)	5
Date of submission (Pre-filled from custom function)	24/NOV/2020 00:19
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

US3432208 (Prod: Brigham and Womens Hospital)

US3432208

Form: Participant Creation

Generated On: 26 Nov 2020 09:27:55

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3432208'	RWS_ENDPOINT ENDPOINT (b) (4) 	20 Aug 2020 13:34:31

US3432208

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:27:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 14:26:46

US3432208

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '20 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	20 Aug 2020 13:34:32

US3432208

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Phoebe Cunningham (b) (4)	20 Aug 2020 14:26:46

US3432208

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:27:55

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	20 Aug 2020 14:26:46

US3432208

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered (b) (6) 1965'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	20 Aug 2020 13:34:33

US3432208

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:27:55

[Age](#)

Audit	User	Time (GMT)
User entered '54'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:06:45

US3432208

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:27:55

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	20 Aug 2020 17:06:45

US3432208

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:27:55

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '54'	System	20 Aug 2020 14:27:04

US3432208

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:27:55

Sex

Audit	User	Time (GMT)
User entered 'Male (M)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:06:45

US3432208

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:27:55

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:06:45

US3432208

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:27:55

White

Audit	User	Time (GMT)
User entered '1'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:06:45

US3432208

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:27:55

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:06:45

US3432208

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:27:55

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:06:45

US3432208

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:27:55

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:06:45

US3432208

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:27:55

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:06:45

US3432208

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:27:55

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:06:45

US3432208

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:27:55

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:06:45

US3432208

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:27:55

Unknown

Audit	User	Time (GMT)
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:06:45

US3432208

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:27:55

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:06:45

US3432208

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Phoebe Cunningham (b) (4)	20 Aug 2020 14:27:04

US3432208

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	20 Aug 2020 14:27:04

US3432208

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '2020'	System	20 Aug 2020 14:27:04

US3432208

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:27:55

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	Phoebe Cunningham (b) (4)	20 Aug 2020 14:27:04

US3432208

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 14:27:04

US3432208

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 14:27:04

US3432208

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:27:55

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 14:27:04

US3432208

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:27:55

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 14:27:04

US3432208

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:27:55

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	20 Aug 2020 13:34:32

US3432208

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:27:55

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 14:27:09

US3432208

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 14:27:09

US3432208

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:27:55

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:17:17

US3432208

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:27:55

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 17:19:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 17:19:20
Data point term sent to Coder	System	20 Aug 2020 17:18:40
User entered 'Hypertension'	Phoebe Cunningham	20 Aug 2020 17:18:00
	(b) (4)	

US3432208

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'un UNK 2000'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:18:00

US3432208

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:18:00

US3432208

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:27:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 17:18:21
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Aug 2020 17:18:21
User entered 'Yes (Y)' reason for change: Data Entry Error	Phoebe Cunningham (b) (4)	20 Aug 2020 17:18:21
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Aug 2020 17:18:00
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:18:00

US3432208

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:18:00

US3432208

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:27:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:18:00

US3432208

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'Jan 2000'	System	20 Aug 2020 17:18:00

US3432208

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '2000'	System	20 Aug 2020 17:18:00

US3432208

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 17:18:00

US3432208

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 17:18:00

US3432208

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:27:55

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 17:20:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 17:20:26
Data point term sent to Coder	System	20 Aug 2020 17:19:42
User entered 'Type II Diabetes'	Phoebe Cunningham	20 Aug 2020 17:18:44
	(b) (4)	

US3432208

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:18:44

US3432208

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:18:44

US3432208

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:27:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:18:44

US3432208

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:18:44

US3432208

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:27:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:18:44

US3432208

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	20 Aug 2020 17:18:44

US3432208

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '2018'	System	20 Aug 2020 17:18:44

US3432208

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 17:18:44

US3432208

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 17:18:44

US3432208

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:27:55

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 17:20:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 17:20:24
Data point term sent to Coder	System	20 Aug 2020 17:19:43
User entered 'Depression'	Phoebe Cunningham	20 Aug 2020 17:19:03
	(b) (4)	

US3432208

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:19:03

US3432208

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:19:03

US3432208

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:27:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:19:03

US3432208

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:19:03

US3432208

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:27:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:19:03

US3432208

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	20 Aug 2020 17:19:03

US3432208

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '2015'	System	20 Aug 2020 17:19:03

US3432208

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 17:19:03

US3432208

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 17:19:03

US3432208

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:27:55

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Dyspepsia - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 17:21:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 17:21:21
Data point term sent to Coder	System	20 Aug 2020 17:20:45
User entered 'Dyspepsia'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:20:01

US3432208

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'un UNK 2017'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:20:01

US3432208

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:20:01

US3432208

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:27:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:20:01

US3432208

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:20:01

US3432208

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:27:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:20:01

US3432208

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'Jan 2017'	System	20 Aug 2020 17:20:01

US3432208

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '2017'	System	20 Aug 2020 17:20:01

US3432208

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 17:20:01

US3432208

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 17:20:01

US3432208

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:27:55

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Gastrointestinal therapeutic procedures NEC, PT: Metabolic surgery, LLT: Bariatric surgery - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 17:22:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 17:22:28
Data point term sent to Coder	System	20 Aug 2020 17:21:51
User entered 'Bariatric surgery'	Phoebe Cunningham	20 Aug 2020 17:21:31
	(b) (4)	

US3432208

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '31 Oct 2019'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:21:31

US3432208

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:21:31

US3432208

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:27:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:21:31

US3432208

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '31 Oct 2019'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:21:31

US3432208

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:27:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:21:31

US3432208

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'Oct 2019'	System	20 Aug 2020 17:21:31

US3432208

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '2019'	System	20 Aug 2020 17:21:31

US3432208

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'Oct 2019'	System	20 Aug 2020 17:21:31

US3432208

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '2019'	System	20 Aug 2020 17:21:31

US3432208

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:27:55

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 16:56:16
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 operation, LLT: Spinal operation - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 11:44:30
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	(b) (4)	22 Oct 2020 11:44:30
Data point term sent to Coder	System	22 Oct 2020 00:17:42
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated' (Site from DM).	Megan Powell (b) (4)	22 Oct 2020 00:17:04
Coding entries removed.	(b) (4)	
	Megan Powell (b) (4)	22 Oct 2020 00:16:59
User entered 'SPINE CORRECTIVE SURGERY' reason for change: Data Entry Error	(b) (4)	
	Megan Powell (b) (4)	22 Oct 2020 00:16:59
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured as a separate entry on the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 04:28:37
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 operation, LLT: Spinal operation - version MedDRA\23.0.	Coder Import (b) (4)	20 Aug 2020 17:24:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	20 Aug 2020 17:24:29
Data point term sent to Coder	System	20 Aug 2020 17:22:53
User entered 'Spine surgery'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:21:57

US3432208

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '17 Jun 2019'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:21:57

US3432208

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:21:57

US3432208

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:27:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:21:57

US3432208

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '17 Jun 2019'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:21:57

US3432208

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:27:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:21:57

US3432208

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'Jun 2019'	System	20 Aug 2020 17:21:57

US3432208

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '2019'	System	20 Aug 2020 17:21:57

US3432208

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'Jun 2019'	System	20 Aug 2020 17:21:57

US3432208

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '2019'	System	20 Aug 2020 17:21:57

US3432208

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:27:55

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please specify the location of Rash. Update Med History eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 07:21:46
Query 'Per DM CLR: Please specify the location of Rash. Update Med History eCRF as appropriate.' answered with 'Per clinician, the presentation of this allergy is a rash.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 16:34:12
User opened query 'Per DM CLR: Please specify the location of Rash. Update Med History eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 04:29:15
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis ascribed to specific agent, PT: Drug eruption, LLT: Allergic drug rash - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:11:42
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 19:11:42
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to antibiotics - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:55:36
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:55:36
Data point term sent to Coder	System	20 Aug 2020 17:22:54
User entered 'Clindamycin allergy (rash)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:22:33

US3432208

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:22:33

US3432208

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:22:33

US3432208

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:27:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:22:33

US3432208

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:22:33

US3432208

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:27:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:22:33

US3432208

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	20 Aug 2020 17:22:33

US3432208

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '2015'	System	20 Aug 2020 17:22:33

US3432208

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 17:22:33

US3432208

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 17:22:33

US3432208

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:27:55

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis ascribed to specific agent, PT: Drug eruption, LLT: Drug rash - version MedDRA\23.0.	Coder Import (b) (4)	20 Nov 2020 17:41:01
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	20 Nov 2020 17:41:01
User closed query 'Per DM CLR: Please specify the location of Rash. Update Med History eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 07:22:12
Query 'Per DM CLR: Please specify the location of Rash. Update Med History eCRF as appropriate.' answered with 'Per clinician, the presentation of this allergy is a rash.' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 16:34:23
User opened query 'Per DM CLR: Please specify the location of Rash. Update Med History eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 04:29:28
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis ascribed to specific agent, PT: Drug eruption, LLT: Allergic drug rash - version MedDRA\23.0.	Coder Import (b) (4)	16 Sep 2020 19:10:44
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	16 Sep 2020 19:10:44
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Allergic reaction to antibiotics - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 18:55:16
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 18:55:16
Data point term sent to Coder	System	20 Aug 2020 17:23:57
User entered 'CIPROFLOX (rash)' reason for change: Data Entry Error	Phoebe Cunningham (b) (4)	20 Aug 2020 17:23:38
User entered 'Ciproflox'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:23:17

US3432208

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'un UNK 2015'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:23:17

US3432208

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:23:17

US3432208

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:27:55

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:23:17

US3432208

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:23:17

US3432208

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:27:55

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:23:17

US3432208

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'Jan 2015'	System	20 Aug 2020 17:23:17

US3432208

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '2015'	System	20 Aug 2020 17:23:17

US3432208

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 17:23:17

US3432208

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 17:23:17

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:12:06

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:12:06

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '9:40'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:12:06

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '20 Aug 2020 9:40'	System	20 Aug 2020 17:12:06

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:55

Height (xxx.x)

Audit	User	Time (GMT)
User entered '161.6' cm	Phoebe Cunningham	20 Aug 2020 17:12:06
	(b) (4)	
DataPoint set to visible.	System	20 Aug 2020 14:27:09

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '78.5' kg	Phoebe Cunningham	20 Aug 2020 17:12:06
	(b) (4)	
DataPoint set to visible.	System	20 Aug 2020 14:27:09

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:55

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '30.05986'	System	17 Sep 2020 00:15:37
User entered '30.1'	System	20 Aug 2020 17:12:06
DataPoint set to visible.	System	20 Aug 2020 14:27:09

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:55

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	20 Aug 2020 17:12:06
DataPoint set to visible.	System	20 Aug 2020 14:27:09

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:55

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:12:06

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:55

[Route of measurement](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 18:37:01
Query 'Data is required. Please provide.' answered with 'N/A' (Site from System).	Phoebe Cunningham (b) (4)	20 Aug 2020 17:12:13
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 17:12:06
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:12:06

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:55

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:12:06

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:12:06

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:55

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	20 Aug 2020 17:12:06

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:12:06

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	20 Aug 2020 17:12:06

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:12:06

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Aug 2020 17:12:06

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:12:06

US3432208

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Aug 2020 17:12:06

US3432208

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:27:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 14:27:24

US3432208

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:27:55

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Phoebe Cunningham (b) (4)	20 Aug 2020 14:27:24

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:55

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)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:55

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)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:55

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)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:55

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)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:55

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)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:55

[Other](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:55

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:55

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:55

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'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '1'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:55

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'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:55

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Phoebe Cunningham	20 Aug 2020 17:07:15
	(b) (4)	

US3432208

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:27:55

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:07:15

US3432208

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:27:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 14:37:50

US3432208

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Phoebe Cunningham (b) (4)	20 Aug 2020 14:37:50

US3432208

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Phoebe Cunningham (b) (4)	20 Aug 2020 14:37:50

US3432208

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:27:55

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	20 Aug 2020 14:37:50

US3432208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '20 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	20 Aug 2020 14:05:01

US3432208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:48:16
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:48:16
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Aug 2020 14:05:01
User entered '144051' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) 	20 Aug 2020 14:05:01

US3432208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	20 Aug 2020 14:05:01

US3432208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:27:55

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)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:12:39

US3432208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:12:39

US3432208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:27:55

Severe obesity (body mass index $\geq$ 40kg/m²)

Audit	User	Time (GMT)
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:12:39

US3432208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:27:55

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:12:39

US3432208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:27:55

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:12:39

US3432208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:36:39
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:41:29

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:27:55

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Phoebe Cunningham	20 Aug 2020 17:14:50
	(b) (4)	

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:27:55

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Phoebe Cunningham	20 Aug 2020 17:14:50
	(b) (4)	

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:27:55

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Phoebe Cunningham	20 Aug 2020 17:14:50
	(b) (4)	

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:27:55

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Phoebe Cunningham	20 Aug 2020 17:14:50
	(b) (4)	

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:55

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '9:40'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '20 Aug 2020 9:40'	System	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:55

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.4' C	Phoebe Cunningham	20 Aug 2020 17:14:50
	(b) (4)	

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:55

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:55

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:55

Pulse (xxx)

Audit	User	Time (GMT)
User entered '53'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:55

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '14'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '140'	Phoebe Cunningham	20 Aug 2020 17:14:50
	(b) (4)	

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '79'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:27:55

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Phoebe Cunningham	20 Aug 2020 17:14:50
	(b) (4)	

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:27:55

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Phoebe Cunningham	20 Aug 2020 17:14:50
	(b) (4)	

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:55

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	20 Aug 2020 18:37:17
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'per protocol post-dose vitals can be assessed 30 minutes following dosage' (Site from System).	Phoebe Cunningham (b) (4)	20 Aug 2020 17:15:13
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	System	20 Aug 2020 17:14:50
User entered '12:16'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:16'	System	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:55

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.3' C	Phoebe Cunningham	20 Aug 2020 17:14:50
	(b) (4)	

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:55

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:55

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '51'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:55

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '14'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '141'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '82'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Aug 2020 17:14:50

US3432208

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:27:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 14:38:40

US3432208

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:27:55

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 14:38:40

US3432208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:27:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 16:02:36

US3432208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:27:55

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 16:02:36

US3432208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 16:02:36

US3432208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:27:55

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	20 Aug 2020 16:02:36

US3432208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:27:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Phoebe Cunningham (b) (4)	20 Aug 2020 16:02:36

US3432208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '11:45'	Phoebe Cunningham (b) (4)	20 Aug 2020 16:02:36

US3432208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '20 Aug 2020 11:45'	System	20 Aug 2020 16:02:36

US3432208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Phoebe Cunningham (b) (4)	20 Aug 2020 16:02:36

US3432208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	20 Aug 2020 16:02:36

US3432208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	20 Aug 2020 16:02:36

US3432208

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:27:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:15:48

US3432208

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:27:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:15:48

US3432208

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:27:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '10:29'	Phoebe Cunningham	20 Aug 2020 17:15:48
	(b) (4)	

US3432208

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '20 Aug 2020 10:29'	System	20 Aug 2020 17:15:48

US3432208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:27:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '20 Aug 2020'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:16:44

US3432208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:27:55

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:16:44

US3432208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:27:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:16:44

US3432208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:27:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '10:16'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:16:44

US3432208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '20 Aug 2020 10:16'	System	20 Aug 2020 17:16:44

US3432208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:27:55

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:16:44

US3432208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:27:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:16:44

US3432208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:27:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:16:44

US3432208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 17:16:44

US3432208

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:16:50

US3432208

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:27:55

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 17:16:50

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T12:22:14', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f0b430e9-d476-4c8b-818c-5861c12104e3'	System	20 Aug 2020 16:22:44
User entered 'Yes (Y)'	System	20 Aug 2020 16:22:44

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T12:22:25', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f0b430e9-d476-4c8b-818c-5861c12104e3'	System	20 Aug 2020 16:22:44
User entered '97.4'	System	20 Aug 2020 16:22:44

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T12:22:35', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f0b430e9-d476-4c8b-818c-5861c12104e3'	System	20 Aug 2020 16:22:44
User entered 'No (N)'	System	20 Aug 2020 16:22:44

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T12:22:41', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f0b430e9-d476-4c8b-818c-5861c12104e3'	System	20 Aug 2020 16:22:44
User entered '20 Aug 2020 12:22'	System	20 Aug 2020 16:22:44

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:05'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 14:35'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T17:25:39', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '58d9bbad-2a84-4de8-bbfd-65ace923d95c'	System	20 Aug 2020 21:26:09
User entered 'Yes (Y)'	System	20 Aug 2020 21:26:09

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T17:25:46', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '58d9bbad-2a84-4de8-bbfd-65ace923d95c'	System	20 Aug 2020 21:26:09
User entered '97.7'	System	20 Aug 2020 21:26:09

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T17:25:55', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '58d9bbad-2a84-4de8-bbfd-65ace923d95c'	System	20 Aug 2020 21:26:09
User entered 'No (N)'	System	20 Aug 2020 21:26:09

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T17:26:05', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '58d9bbad-2a84-4de8-bbfd-65ace923d95c'	System	20 Aug 2020 21:26:09
User entered '20 Aug 2020 17:26'	System	20 Aug 2020 21:26:09

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 15:30'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 2'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-21T12:12:38', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'a6ec9ab9-2bd9-4da4-99a4-bb409294090b'	System	21 Aug 2020 16:12:58
User entered 'Yes (Y)'	System	21 Aug 2020 16:12:58

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-21T12:12:44', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'a6ec9ab9-2bd9-4da4-99a4-bb409294090b'	System	21 Aug 2020 16:12:58
User entered '98.8'	System	21 Aug 2020 16:12:58

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-21T12:12:51', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'a6ec9ab9-2bd9-4da4-99a4-bb409294090b'	System	21 Aug 2020 16:12:58
User entered 'No (N)'	System	21 Aug 2020 16:12:58

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-21T12:12:54', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'a6ec9ab9-2bd9-4da4-99a4-bb409294090b'	System	21 Aug 2020 16:12:58
User entered '21 Aug 2020 12:12'	System	21 Aug 2020 16:12:58

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 3'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-23T08:18:38', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'd4cfd7b-7665-48d9-87b8-e24e2d3a7431'	System	23 Aug 2020 12:19:03
User entered 'Yes (Y)'	System	23 Aug 2020 12:19:03

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-23T08:18:46', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'd4cfd7b-7665-48d9-87b8-e24e2d3a7431'	System	23 Aug 2020 12:19:03
User entered '96.9'	System	23 Aug 2020 12:19:03

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-23T08:18:53', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'd4cfd7b-7665-48d9-87b8-e24e2d3a7431'	System	23 Aug 2020 12:19:03
User entered 'No (N)'	System	23 Aug 2020 12:19:03

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-23T08:18:59', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'd4cfd7b-7665-48d9-87b8-e24e2d3a7431'	System	23 Aug 2020 12:19:03
User entered '23 Aug 2020 08:18'	System	23 Aug 2020 12:19:03

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 4'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-24T11:11:18', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'b135be33-233f-413f-b479-a31012397b74'	System	24 Aug 2020 15:11:37
User entered 'Yes (Y)'	System	24 Aug 2020 15:11:37

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-24T11:11:23', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'b135be33-233f-413f-b479-a31012397b74'	System	24 Aug 2020 15:11:37
User entered '98.5'	System	24 Aug 2020 15:11:37

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-24T11:11:27', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'b135be33-233f-413f-b479-a31012397b74'	System	24 Aug 2020 15:11:37
User entered 'No (N)'	System	24 Aug 2020 15:11:37

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-24T11:11:35', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'b135be33-233f-413f-b479-a31012397b74'	System	24 Aug 2020 15:11:37
User entered '24 Aug 2020 11:11'	System	24 Aug 2020 15:11:37

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 5'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-25T07:59:02', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'fbe40c5e-c459-418c-895c-e2063dd04910'	System	25 Aug 2020 11:59:17
User entered 'Yes (Y)'	System	25 Aug 2020 11:59:17

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-25T07:59:07', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'fbe40c5e-c459-418c-895c-e2063dd04910'	System	25 Aug 2020 11:59:17
User entered '97.7'	System	25 Aug 2020 11:59:17

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-25T07:59:11', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'fbe40c5e-c459-418c-895c-e2063dd04910'	System	25 Aug 2020 11:59:17
User entered 'No (N)'	System	25 Aug 2020 11:59:17

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-25T07:59:15', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'fbe40c5e-c459-418c-895c-e2063dd04910'	System	25 Aug 2020 11:59:17
User entered '25 Aug 2020 07:59'	System	25 Aug 2020 11:59:17

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 6'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-26T07:50:46', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '00331b78-af39-4dd3-a682-0d9cb55e4ac4'	System	26 Aug 2020 11:51:02
User entered 'Yes (Y)'	System	26 Aug 2020 11:51:02

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-26T07:50:51', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '00331b78-af39-4dd3-a682-0d9cb55e4ac4'	System	26 Aug 2020 11:51:02
User entered '97.8'	System	26 Aug 2020 11:51:02

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-26T07:50:58', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '00331b78-af39-4dd3-a682-0d9cb55e4ac4'	System	26 Aug 2020 11:51:02
User entered 'No (N)'	System	26 Aug 2020 11:51:02

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-26T07:51:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '00331b78-af39-4dd3-a682-0d9cb55e4ac4'	System	26 Aug 2020 11:51:02
User entered '26 Aug 2020 07:51'	System	26 Aug 2020 11:51:02

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 7'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-27T07:33:57', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '1fde6999-db3f-40c6-9f87-03b8c7f9ca01'	System	27 Aug 2020 11:34:11
User entered 'Yes (Y)'	System	27 Aug 2020 11:34:11

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-27T07:34:03', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '1fde6999-db3f-40c6-9f87-03b8c7f9ca01'	System	27 Aug 2020 11:34:11
User entered '97.4'	System	27 Aug 2020 11:34:11

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-27T07:34:06', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '1fde6999-db3f-40c6-9f87-03b8c7f9ca01'	System	27 Aug 2020 11:34:11
User entered 'No (N)'	System	27 Aug 2020 11:34:11

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-27T07:34:08', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '1fde6999-db3f-40c6-9f87-03b8c7f9ca01'	System	27 Aug 2020 11:34:11
User entered '27 Aug 2020 07:34'	System	27 Aug 2020 11:34:11

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

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 (9bd8831adf3b531b)', Time: '2020-08-20T12:22:53', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c7a9fd1d-ee95-4f7d-8c36-9cda5617f7f5'	System	20 Aug 2020 16:23:20
User entered 'None (1)'	System	20 Aug 2020 16:23:20

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T12:22:59', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c7a9fd1d-ee95-4f7d-8c36-9cda5617f7f5'	System	20 Aug 2020 16:23:20
User entered 'No (N)'	System	20 Aug 2020 16:23:20

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T12:23:05', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c7a9fd1d-ee95-4f7d-8c36-9cda5617f7f5'	System	20 Aug 2020 16:23:20
User entered 'No (N)'	System	20 Aug 2020 16:23:20

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

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 (9bd8831adf3b531b)', Time: '2020-08-20T12:23:11', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c7a9fd1d-ee95-4f7d-8c36-9cda5617f7f5'	System	20 Aug 2020 16:23:20
User entered 'None (1)'	System	20 Aug 2020 16:23:20

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T12:23:16', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c7a9fd1d-ee95-4f7d-8c36-9cda5617f7f5'	System	20 Aug 2020 16:23:20
User entered '20 Aug 2020 12:23'	System	20 Aug 2020 16:23:20

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:05'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 14:35'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

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 (9bd8831adf3b531b)', Time: '2020-08-20T17:26:20', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'b49ee639-de09-47e6-9667-41d18d636b9a'	System	20 Aug 2020 21:26:44
User entered 'None (1)'	System	20 Aug 2020 21:26:44

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T17:26:29', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'b49ee639-de09-47e6-9667-41d18d636b9a'	System	20 Aug 2020 21:26:44
User entered 'No (N)'	System	20 Aug 2020 21:26:44

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T17:26:33', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'b49ee639-de09-47e6-9667-41d18d636b9a'	System	20 Aug 2020 21:26:44
User entered 'No (N)'	System	20 Aug 2020 21:26:44

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

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 (9bd8831adf3b531b)', Time: '2020-08-20T17:26:39', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'b49ee639-de09-47e6-9667-41d18d636b9a'	System	20 Aug 2020 21:26:44
User entered 'None (1)'	System	20 Aug 2020 21:26:44

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T17:26:42', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'b49ee639-de09-47e6-9667-41d18d636b9a'	System	20 Aug 2020 21:26:44
User entered '20 Aug 2020 17:26'	System	20 Aug 2020 21:26:44

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 15:30'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 2'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:27:55

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 (9bd8831adf3b531b)', Time: '2020-08-21T12:12:59', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'ac2e498b-f8a5-485b-bcf7-6d33e2aa11d7'	System	21 Aug 2020 16:13:42
User entered 'None (1)'	System	21 Aug 2020 16:13:42

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-21T12:13:24', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'ac2e498b-f8a5-485b-bcf7-6d33e2aa11d7'	System	21 Aug 2020 16:13:42
User entered 'No (N)'	System	21 Aug 2020 16:13:42

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-21T12:13:28', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'ac2e498b-f8a5-485b-bcf7-6d33e2aa11d7'	System	21 Aug 2020 16:13:42
User entered 'No (N)'	System	21 Aug 2020 16:13:42

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:27:55

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 (9bd8831adf3b531b)', Time: '2020-08-21T12:13:35', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'ac2e498b-f8a5-485b-bcf7-6d33e2aa11d7'	System	21 Aug 2020 16:13:42
User entered 'None (1)'	System	21 Aug 2020 16:13:42

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-21T12:13:40', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'ac2e498b-f8a5-485b-bcf7-6d33e2aa11d7'	System	21 Aug 2020 16:13:42
User entered '21 Aug 2020 12:13'	System	21 Aug 2020 16:13:42

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 3'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:27:55

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 (9bd8831adf3b531b)', Time: '2020-08-23T08:19:05', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'ce883389-c17e-4173-93c5-872d238f5651'	System	23 Aug 2020 12:19:20
User entered 'None (1)'	System	23 Aug 2020 12:19:20

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-23T08:19:09', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'ce883389-c17e-4173-93c5-872d238f5651'	System	23 Aug 2020 12:19:20
User entered 'No (N)'	System	23 Aug 2020 12:19:20

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-23T08:19:12', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'ce883389-c17e-4173-93c5-872d238f5651'	System	23 Aug 2020 12:19:20
User entered 'No (N)'	System	23 Aug 2020 12:19:20

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:27:55

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 (9bd8831adf3b531b)', Time: '2020-08-23T08:19:16', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'ce883389-c17e-4173-93c5-872d238f5651'	System	23 Aug 2020 12:19:20
User entered 'None (1)'	System	23 Aug 2020 12:19:20

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-23T08:19:19', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'ce883389-c17e-4173-93c5-872d238f5651'	System	23 Aug 2020 12:19:20
User entered '23 Aug 2020 08:19'	System	23 Aug 2020 12:19:20

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 4'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:27:55

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 (9bd8831adf3b531b)', Time: '2020-08-24T11:11:41', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '3ec7ba58-44b3-47bf-9912-500c42c2d93e'	System	24 Aug 2020 15:11:56
User entered 'None (1)'	System	24 Aug 2020 15:11:56

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-24T11:11:44', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '3ec7ba58-44b3-47bf-9912-500c42c2d93e'	System	24 Aug 2020 15:11:56
User entered 'No (N)'	System	24 Aug 2020 15:11:56

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-24T11:11:48', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '3ec7ba58-44b3-47bf-9912-500c42c2d93e'	System	24 Aug 2020 15:11:56
User entered 'No (N)'	System	24 Aug 2020 15:11:56

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:27:55

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 (9bd8831adf3b531b)', Time: '2020-08-24T11:11:51', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '3ec7ba58-44b3-47bf-9912-500c42c2d93e'	System	24 Aug 2020 15:11:56
User entered 'None (1)'	System	24 Aug 2020 15:11:56

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-24T11:11:53', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '3ec7ba58-44b3-47bf-9912-500c42c2d93e'	System	24 Aug 2020 15:11:56
User entered '24 Aug 2020 11:11'	System	24 Aug 2020 15:11:56

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 5'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:27:55

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 (9bd8831adf3b531b)', Time: '2020-08-25T07:59:33', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '1bb0af02-4510-4440-bcc2-134d5de12138'	System	25 Aug 2020 11:59:49
User entered 'None (1)'	System	25 Aug 2020 11:59:49

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-25T07:59:36', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '1bb0af02-4510-4440-bcc2-134d5de12138'	System	25 Aug 2020 11:59:49
User entered 'No (N)'	System	25 Aug 2020 11:59:49

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-25T07:59:40', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '1bb0af02-4510-4440-bcc2-134d5de12138'	System	25 Aug 2020 11:59:49
User entered 'No (N)'	System	25 Aug 2020 11:59:49

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:27:55

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 (9bd8831adf3b531b)', Time: '2020-08-25T07:59:44', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '1bb0af02-4510-4440-bcc2-134d5de12138'	System	25 Aug 2020 11:59:49
User entered 'None (1)'	System	25 Aug 2020 11:59:49

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-25T07:59:47', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '1bb0af02-4510-4440-bcc2-134d5de12138'	System	25 Aug 2020 11:59:49
User entered '25 Aug 2020 07:59'	System	25 Aug 2020 11:59:49

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 6'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:27:55

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 (9bd8831adf3b531b)', Time: '2020-08-26T07:51:06', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '9aa4a407-af17-4988-9cec-63630dedb6d7'	System	26 Aug 2020 11:51:21
User entered 'None (1)'	System	26 Aug 2020 11:51:21

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-26T07:51:10', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '9aa4a407-af17-4988-9cec-63630dedb6d7'	System	26 Aug 2020 11:51:21
User entered 'No (N)'	System	26 Aug 2020 11:51:21

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-26T07:51:13', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '9aa4a407-af17-4988-9cec-63630dedb6d7'	System	26 Aug 2020 11:51:21
User entered 'No (N)'	System	26 Aug 2020 11:51:21

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:27:55

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 (9bd8831adf3b531b)', Time: '2020-08-26T07:51:15', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '9aa4a407-af17-4988-9cec-63630dedb6d7'	System	26 Aug 2020 11:51:21
User entered 'None (1)'	System	26 Aug 2020 11:51:21

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-26T07:51:17', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '9aa4a407-af17-4988-9cec-63630dedb6d7'	System	26 Aug 2020 11:51:21
User entered '26 Aug 2020 07:51'	System	26 Aug 2020 11:51:21

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 7'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:27:55

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 (9bd8831adf3b531b)', Time: '2020-08-27T07:34:13', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'e53dc2e6-54da-4b42-908a-ba2d68e01e4b'	System	27 Aug 2020 11:34:28
User entered 'None (1)'	System	27 Aug 2020 11:34:28

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-27T07:34:16', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'e53dc2e6-54da-4b42-908a-ba2d68e01e4b'	System	27 Aug 2020 11:34:28
User entered 'No (N)'	System	27 Aug 2020 11:34:28

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-27T07:34:18', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'e53dc2e6-54da-4b42-908a-ba2d68e01e4b'	System	27 Aug 2020 11:34:28
User entered 'No (N)'	System	27 Aug 2020 11:34:28

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:27:55

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 (9bd8831adf3b531b)', Time: '2020-08-27T07:34:21', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'e53dc2e6-54da-4b42-908a-ba2d68e01e4b'	System	27 Aug 2020 11:34:28
User entered 'None (1)'	System	27 Aug 2020 11:34:28

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-27T07:34:23', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'e53dc2e6-54da-4b42-908a-ba2d68e01e4b'	System	27 Aug 2020 11:34:28
User entered '27 Aug 2020 07:34'	System	27 Aug 2020 11:34:28

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T12:23:47', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '4aec09a1-b9da-4e1d-901f-bf4fab2a50cc'	System	20 Aug 2020 16:24:24
User entered 'None (0)'	System	20 Aug 2020 16:24:24

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T12:23:51', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '4aec09a1-b9da-4e1d-901f-bf4fab2a50cc'	System	20 Aug 2020 16:24:24
User entered 'None (0)'	System	20 Aug 2020 16:24:24

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T12:23:56', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '4aec09a1-b9da-4e1d-901f-bf4fab2a50cc'	System	20 Aug 2020 16:24:24
User entered 'None (0)'	System	20 Aug 2020 16:24:24

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T12:24:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '4aec09a1-b9da-4e1d-901f-bf4fab2a50cc'	System	20 Aug 2020 16:24:24
User entered 'None (0)'	System	20 Aug 2020 16:24:24

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T12:24:02', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '4aec09a1-b9da-4e1d-901f-bf4fab2a50cc'	System	20 Aug 2020 16:24:24
User entered 'None (0)'	System	20 Aug 2020 16:24:24

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T12:24:05', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '4aec09a1-b9da-4e1d-901f-bf4fab2a50cc'	System	20 Aug 2020 16:24:24
User entered 'None (0)'	System	20 Aug 2020 16:24:24

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

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 (9bd8831adf3b531b)', Time: '2020-08-20T12:24:15', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '4aec09a1-b9da-4e1d-901f-bf4fab2a50cc'	System	20 Aug 2020 16:24:24
User entered 'No (N)'	System	20 Aug 2020 16:24:24

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T12:24:19', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '4aec09a1-b9da-4e1d-901f-bf4fab2a50cc'	System	20 Aug 2020 16:24:24
User entered '20 Aug 2020 12:24'	System	20 Aug 2020 16:24:24

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 12:05'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 14:35'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T17:26:49', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '78274249-a95d-4523-917d-fd7727937468'	System	20 Aug 2020 21:27:17
User entered 'None (0)'	System	20 Aug 2020 21:27:17

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T17:26:52', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '78274249-a95d-4523-917d-fd7727937468'	System	20 Aug 2020 21:27:17
User entered 'None (0)'	System	20 Aug 2020 21:27:17

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T17:26:55', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '78274249-a95d-4523-917d-fd7727937468'	System	20 Aug 2020 21:27:17
User entered 'None (0)'	System	20 Aug 2020 21:27:17

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T17:26:58', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '78274249-a95d-4523-917d-fd7727937468'	System	20 Aug 2020 21:27:17
User entered 'None (0)'	System	20 Aug 2020 21:27:17

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T17:27:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '78274249-a95d-4523-917d-fd7727937468'	System	20 Aug 2020 21:27:17
User entered 'None (0)'	System	20 Aug 2020 21:27:17

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T17:27:03', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '78274249-a95d-4523-917d-fd7727937468'	System	20 Aug 2020 21:27:17
User entered 'None (0)'	System	20 Aug 2020 21:27:17

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

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 (9bd8831adf3b531b)', Time: '2020-08-20T17:27:09', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '78274249-a95d-4523-917d-fd7727937468'	System	20 Aug 2020 21:27:17
User entered 'No (N)'	System	20 Aug 2020 21:27:17

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-20T17:27:12', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '78274249-a95d-4523-917d-fd7727937468'	System	20 Aug 2020 21:27:17
User entered '20 Aug 2020 17:27'	System	20 Aug 2020 21:27:17

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Aug 2020 15:30'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 2'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-21T12:13:54', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'a05bea3a-ac69-4e27-83aa-72e25c5c7d77'	System	21 Aug 2020 16:14:19
User entered 'None (0)'	System	21 Aug 2020 16:14:19

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-21T12:13:57', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'a05bea3a-ac69-4e27-83aa-72e25c5c7d77'	System	21 Aug 2020 16:14:19
User entered 'None (0)'	System	21 Aug 2020 16:14:19

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-21T12:14:01', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'a05bea3a-ac69-4e27-83aa-72e25c5c7d77'	System	21 Aug 2020 16:14:19
User entered 'None (0)'	System	21 Aug 2020 16:14:19

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-21T12:14:03', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'a05bea3a-ac69-4e27-83aa-72e25c5c7d77'	System	21 Aug 2020 16:14:19
User entered 'None (0)'	System	21 Aug 2020 16:14:19

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-21T12:14:06', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'a05bea3a-ac69-4e27-83aa-72e25c5c7d77'	System	21 Aug 2020 16:14:19
User entered 'None (0)'	System	21 Aug 2020 16:14:19

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-21T12:14:08', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'a05bea3a-ac69-4e27-83aa-72e25c5c7d77'	System	21 Aug 2020 16:14:19
User entered 'None (0)'	System	21 Aug 2020 16:14:19

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:55

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 (9bd8831adf3b531b)', Time: '2020-08-21T12:14:13', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'a05bea3a-ac69-4e27-83aa-72e25c5c7d77'	System	21 Aug 2020 16:14:19
User entered 'No (N)'	System	21 Aug 2020 16:14:19

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-21T12:14:15', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'a05bea3a-ac69-4e27-83aa-72e25c5c7d77'	System	21 Aug 2020 16:14:19
User entered '21 Aug 2020 12:14'	System	21 Aug 2020 16:14:19

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 3'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-23T08:19:24', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '8075f14f-3ba3-466c-b003-d01398eab8fe'	System	23 Aug 2020 12:19:57
User entered 'None (0)'	System	23 Aug 2020 12:19:57

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-23T08:19:27', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '8075f14f-3ba3-466c-b003-d01398eab8fe'	System	23 Aug 2020 12:19:57
User entered 'None (0)'	System	23 Aug 2020 12:19:57

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-23T08:19:30', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '8075f14f-3ba3-466c-b003-d01398eab8fe'	System	23 Aug 2020 12:19:57
User entered 'None (0)'	System	23 Aug 2020 12:19:57

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-23T08:19:34', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '8075f14f-3ba3-466c-b003-d01398eab8fe'	System	23 Aug 2020 12:19:57
User entered 'None (0)'	System	23 Aug 2020 12:19:57

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-23T08:19:36', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '8075f14f-3ba3-466c-b003-d01398eab8fe'	System	23 Aug 2020 12:19:57
User entered 'None (0)'	System	23 Aug 2020 12:19:57

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-23T08:19:38', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '8075f14f-3ba3-466c-b003-d01398eab8fe'	System	23 Aug 2020 12:19:57
User entered 'None (0)'	System	23 Aug 2020 12:19:57

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:55

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 (9bd8831adf3b531b)', Time: '2020-08-23T08:19:40', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '8075f14f-3ba3-466c-b003-d01398eab8fe'	System	23 Aug 2020 12:19:57
User entered 'No (N)'	System	23 Aug 2020 12:19:57

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-23T08:19:44', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '8075f14f-3ba3-466c-b003-d01398eab8fe'	System	23 Aug 2020 12:19:57
User entered '23 Aug 2020 08:19'	System	23 Aug 2020 12:19:57

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 4'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-24T11:11:57', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c2da336b-b910-4afd-96f6-69024d58b014'	System	24 Aug 2020 15:12:24
User entered 'None (0)'	System	24 Aug 2020 15:12:24

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-24T11:12:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c2da336b-b910-4afd-96f6-69024d58b014'	System	24 Aug 2020 15:12:24
User entered 'None (0)'	System	24 Aug 2020 15:12:24

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-24T11:12:02', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c2da336b-b910-4afd-96f6-69024d58b014'	System	24 Aug 2020 15:12:24
User entered 'None (0)'	System	24 Aug 2020 15:12:24

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-24T11:12:05', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c2da336b-b910-4afd-96f6-69024d58b014'	System	24 Aug 2020 15:12:24
User entered 'None (0)'	System	24 Aug 2020 15:12:24

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-24T11:12:08', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c2da336b-b910-4afd-96f6-69024d58b014'	System	24 Aug 2020 15:12:24
User entered 'None (0)'	System	24 Aug 2020 15:12:24

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-24T11:12:10', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c2da336b-b910-4afd-96f6-69024d58b014'	System	24 Aug 2020 15:12:24
User entered 'None (0)'	System	24 Aug 2020 15:12:24

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:55

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 (9bd8831adf3b531b)', Time: '2020-08-24T11:12:17', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c2da336b-b910-4afd-96f6-69024d58b014'	System	24 Aug 2020 15:12:24
User entered 'No (N)'	System	24 Aug 2020 15:12:24

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-24T11:12:20', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c2da336b-b910-4afd-96f6-69024d58b014'	System	24 Aug 2020 15:12:24
User entered '24 Aug 2020 11:12'	System	24 Aug 2020 15:12:24

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 5'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-25T07:59:51', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '5762abdf-72f3-4f2f-954f-2b113209d9ba'	System	25 Aug 2020 12:00:16
User entered 'None (0)'	System	25 Aug 2020 12:00:16

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-25T07:59:57', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '5762abdf-72f3-4f2f-954f-2b113209d9ba'	System	25 Aug 2020 12:00:16
User entered 'None (0)'	System	25 Aug 2020 12:00:16

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-25T08:00:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '5762abdf-72f3-4f2f-954f-2b113209d9ba'	System	25 Aug 2020 12:00:16
User entered 'None (0)'	System	25 Aug 2020 12:00:16

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-25T08:00:02', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '5762abdf-72f3-4f2f-954f-2b113209d9ba'	System	25 Aug 2020 12:00:16
User entered 'None (0)'	System	25 Aug 2020 12:00:16

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-25T08:00:04', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '5762abdf-72f3-4f2f-954f-2b113209d9ba'	System	25 Aug 2020 12:00:16
User entered 'None (0)'	System	25 Aug 2020 12:00:16

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-25T08:00:06', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '5762abdf-72f3-4f2f-954f-2b113209d9ba'	System	25 Aug 2020 12:00:16
User entered 'None (0)'	System	25 Aug 2020 12:00:16

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:55

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 (9bd8831adf3b531b)', Time: '2020-08-25T08:00:08', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '5762abdf-72f3-4f2f-954f-2b113209d9ba'	System	25 Aug 2020 12:00:16
User entered 'No (N)'	System	25 Aug 2020 12:00:16

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-25T08:00:11', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '5762abdf-72f3-4f2f-954f-2b113209d9ba'	System	25 Aug 2020 12:00:16
User entered '25 Aug 2020 08:00'	System	25 Aug 2020 12:00:16

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 6'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-26T07:51:23', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '337c4bbf-10ba-48dc-b140-35826491d3a2'	System	26 Aug 2020 11:51:42
User entered 'None (0)'	System	26 Aug 2020 11:51:42

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-26T07:51:24', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '337c4bbf-10ba-48dc-b140-35826491d3a2'	System	26 Aug 2020 11:51:42
User entered 'None (0)'	System	26 Aug 2020 11:51:42

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-26T07:51:26', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '337c4bbf-10ba-48dc-b140-35826491d3a2'	System	26 Aug 2020 11:51:42
User entered 'None (0)'	System	26 Aug 2020 11:51:42

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-26T07:51:29', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '337c4bbf-10ba-48dc-b140-35826491d3a2'	System	26 Aug 2020 11:51:42
User entered 'None (0)'	System	26 Aug 2020 11:51:42

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-26T07:51:31', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '337c4bbf-10ba-48dc-b140-35826491d3a2'	System	26 Aug 2020 11:51:42
User entered 'None (0)'	System	26 Aug 2020 11:51:42

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-26T07:51:33', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '337c4bbf-10ba-48dc-b140-35826491d3a2'	System	26 Aug 2020 11:51:42
User entered 'None (0)'	System	26 Aug 2020 11:51:42

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:55

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 (9bd8831adf3b531b)', Time: '2020-08-26T07:51:35', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '337c4bbf-10ba-48dc-b140-35826491d3a2'	System	26 Aug 2020 11:51:42
User entered 'No (N)'	System	26 Aug 2020 11:51:42

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-26T07:51:37', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '337c4bbf-10ba-48dc-b140-35826491d3a2'	System	26 Aug 2020 11:51:42
User entered '26 Aug 2020 07:51'	System	26 Aug 2020 11:51:42

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 7'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-27T07:34:28', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '3cd70a8f-d3f3-436f-864b-4fdcc9794aae'	System	27 Aug 2020 11:34:47
User entered 'None (0)'	System	27 Aug 2020 11:34:47

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-27T07:34:30', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '3cd70a8f-d3f3-436f-864b-4fdcc9794aae'	System	27 Aug 2020 11:34:47
User entered 'None (0)'	System	27 Aug 2020 11:34:47

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-27T07:34:32', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '3cd70a8f-d3f3-436f-864b-4fdcc9794aae'	System	27 Aug 2020 11:34:47
User entered 'None (0)'	System	27 Aug 2020 11:34:47

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-27T07:34:34', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '3cd70a8f-d3f3-436f-864b-4fdcc9794aae'	System	27 Aug 2020 11:34:47
User entered 'None (0)'	System	27 Aug 2020 11:34:47

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-27T07:34:36', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '3cd70a8f-d3f3-436f-864b-4fdcc9794aae'	System	27 Aug 2020 11:34:47
User entered 'None (0)'	System	27 Aug 2020 11:34:47

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-27T07:34:38', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '3cd70a8f-d3f3-436f-864b-4fdcc9794aae'	System	27 Aug 2020 11:34:47
User entered 'None (0)'	System	27 Aug 2020 11:34:47

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:55

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 (9bd8831adf3b531b)', Time: '2020-08-27T07:34:43', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '3cd70a8f-d3f3-436f-864b-4fdcc9794aae'	System	27 Aug 2020 11:34:47
User entered 'No (N)'	System	27 Aug 2020 11:34:47

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (9bd8831adf3b531b)', Time: '2020-08-27T07:34:45', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '3cd70a8f-d3f3-436f-864b-4fdcc9794aae'	System	27 Aug 2020 11:34:47
User entered '27 Aug 2020 07:34'	System	27 Aug 2020 11:34:47

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 16:02:36

US3432208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:55

[Was Contact Attempted?](#)

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

US3432208

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:55

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '27 Aug 2020'	Phoebe Cunningham (b) (4)	27 Aug 2020 18:24:35

US3432208

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	27 Aug 2020 18:24:35

US3432208

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:55

[Comments](#)

If Contact Not Made, please provide Comments

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

US3432208

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	27 Aug 2020 18:24:39

US3432208

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:55

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 18:24:39

US3432208

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	03 Sep 2020 19:14:45

US3432208

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:55

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '03 Sep 2020' reason for change: Data Entry Error	Xhoi Mitre (b) (4)	10 Nov 2020 15:09:52
User entered '3 Sep 2020'	Phoebe Cunningham (b) (4)	03 Sep 2020 19:14:45

US3432208

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	03 Sep 2020 19:14:45

US3432208

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	03 Sep 2020 19:14:45

US3432208

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	03 Sep 2020 19:14:39

US3432208

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:55

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Sep 2020 19:14:39

US3432208

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 19:17:02

US3432208

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:55

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 19:17:02

US3432208

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	10 Sep 2020 19:17:02

US3432208

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 19:17:02

US3432208

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Cauley (b) (4) (b) (4)	17 Sep 2020 13:58:54

US3432208

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:55

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 13:58:54

US3432208

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:27:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Cauley (b) (4) (b) (4)	17 Sep 2020 13:59:22

US3432208

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Jessica Cauley (b) (4) (b) (4)	17 Sep 2020 13:59:22

US3432208

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Jessica Cauley (b) (4) (b) (4)	17 Sep 2020 13:59:22

US3432208

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:27:55

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	17 Sep 2020 13:59:22

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:55

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '8:26'	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '17 Sep 2020 8:26'	System	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:55

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.8' C	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:55

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:55

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '71'	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:55

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '12'	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '138'	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '91'	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:27:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:55

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '10:19'	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '17 Sep 2020 10:19'	System	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:55

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '37.0' C	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:55

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:55

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '73'	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:55

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '20'	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '138'	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '93'	(b) (4), (b) (6)	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:27:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	17 Sep 2020 17:08:35

US3432208

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:27:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 17:03:04

US3432208

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:27:55

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 17:03:04

US3432208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:27:55

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Cauley (b) (4) (b) (4)	17 Sep 2020 13:59:44

US3432208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:27:55

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	Jessica Cauley (b) (4) (b) (4)	17 Sep 2020 13:59:44

US3432208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered empty.	Jessica Cauley (b) (4) (b) (4)	17 Sep 2020 13:59:44

US3432208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:27:55

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	17 Sep 2020 13:59:44

US3432208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:27:55

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Jessica Cauley (b) (4) (b) (4)	17 Sep 2020 13:59:44

US3432208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '09:49'	Jessica Cauley (b) (4) (b) (4)	17 Sep 2020 13:59:44

US3432208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '17 Sep 2020 09:49'	System	17 Sep 2020 13:59:44

US3432208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'Left Arm (LEFT ARM)'	Jessica Cauley (b) (4) (b) (4)	17 Sep 2020 13:59:44

US3432208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	17 Sep 2020 13:59:44

US3432208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	17 Sep 2020 13:59:44

US3432208

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:27:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Cauley (b) (4) (b) (4)	17 Sep 2020 19:52:40

US3432208

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Jessica Cauley (b) (4) (b) (4)	17 Sep 2020 19:52:40

US3432208

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '09:30'	Jessica Cauley (b) (4) (b) (4)	17 Sep 2020 19:52:40

US3432208

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '17 Sep 2020 09:30'	System	17 Sep 2020 19:52:40

US3432208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:27:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	Jessica Cauley (b) (4) (b) (4)	17 Sep 2020 19:52:55

US3432208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:27:55

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jessica Cauley (b) (4)	17 Sep 2020 19:52:55

US3432208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:27:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Jessica Cauley (b) (4) (b) (4)	17 Sep 2020 19:52:55

US3432208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:27:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '09:35'	Jessica Cauley (b) (4) (b) (4)	17 Sep 2020 19:52:55

US3432208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '17 Sep 2020 09:35'	System	17 Sep 2020 19:52:55

US3432208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:27:55

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jessica Cauley (b) (4)	17 Sep 2020 19:52:55

US3432208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:27:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Jessica Cauley (b) (4) (b) (4)	17 Sep 2020 19:52:55

US3432208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:27:55

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Jessica Cauley (b) (4) (b) (4)	17 Sep 2020 19:52:55

US3432208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 19:52:55

US3432208

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 17:03:21

US3432208

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:55

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Sep 2020 17:03:21

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-17T10:26:23', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '97d5b9c7-4001-4827-af02-1b12da9dd3fe'	System	17 Sep 2020 14:26:41
User entered 'Yes (Y)'	System	17 Sep 2020 14:26:41

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-17T10:26:29', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '97d5b9c7-4001-4827-af02-1b12da9dd3fe'	System	17 Sep 2020 14:26:41
User entered '98.6'	System	17 Sep 2020 14:26:41

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-17T10:26:35', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '97d5b9c7-4001-4827-af02-1b12da9dd3fe'	System	17 Sep 2020 14:26:41
User entered 'No (N)'	System	17 Sep 2020 14:26:41

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-17T10:26:38', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '97d5b9c7-4001-4827-af02-1b12da9dd3fe'	System	17 Sep 2020 14:26:41
User entered '17 Sep 2020 10:26'	System	17 Sep 2020 14:26:41

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 10:09'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:39'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-18T09:50:30', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'db8e6889-6c41-4ff1-b6d1-26d85e973477'	System	18 Sep 2020 13:51:01
User entered 'Yes (Y)'	System	18 Sep 2020 13:51:01

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-18T09:50:35', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'db8e6889-6c41-4ff1-b6d1-26d85e973477'	System	18 Sep 2020 13:51:01
User entered '97.5'	System	18 Sep 2020 13:51:01

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-18T09:50:50', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'db8e6889-6c41-4ff1-b6d1-26d85e973477'	System	18 Sep 2020 13:51:01
User entered 'No (N)'	System	18 Sep 2020 13:51:01

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-18T09:50:54', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'db8e6889-6c41-4ff1-b6d1-26d85e973477'	System	18 Sep 2020 13:51:01
User entered '18 Sep 2020 09:50'	System	18 Sep 2020 13:51:01

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 13:34'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 2'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-19T11:21:10', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '8401925d-e535-4530-82b7-1ca7fc441d3a'	System	19 Sep 2020 15:21:39
User entered 'Yes (Y)'	System	19 Sep 2020 15:21:39

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-19T11:21:27', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '8401925d-e535-4530-82b7-1ca7fc441d3a'	System	19 Sep 2020 15:21:39
User entered '97.6'	System	19 Sep 2020 15:21:39

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-19T11:21:34', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '8401925d-e535-4530-82b7-1ca7fc441d3a'	System	19 Sep 2020 15:21:39
User entered 'No (N)'	System	19 Sep 2020 15:21:39

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-19T11:21:37', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '8401925d-e535-4530-82b7-1ca7fc441d3a'	System	19 Sep 2020 15:21:39
User entered '19 Sep 2020 11:21'	System	19 Sep 2020 15:21:39

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 3'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T08:32:14', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f96a9dce-09b0-4ec0-8425-6ce9d6aa3a02'	System	20 Sep 2020 12:32:32
User entered 'Yes (Y)'	System	20 Sep 2020 12:32:32

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T08:32:19', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f96a9dce-09b0-4ec0-8425-6ce9d6aa3a02'	System	20 Sep 2020 12:32:32
User entered '97.5'	System	20 Sep 2020 12:32:32

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T08:32:23', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f96a9dce-09b0-4ec0-8425-6ce9d6aa3a02'	System	20 Sep 2020 12:32:32
User entered 'No (N)'	System	20 Sep 2020 12:32:32

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T08:32:29', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f96a9dce-09b0-4ec0-8425-6ce9d6aa3a02'	System	20 Sep 2020 12:32:32
User entered '20 Sep 2020 08:32'	System	20 Sep 2020 12:32:32

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 4'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T22:36:33', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'afe42b5b-df06-436e-8409-9c09a9f80388'	System	21 Sep 2020 02:36:55
User entered 'Yes (Y)'	System	21 Sep 2020 02:36:55

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T22:36:41', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'afe42b5b-df06-436e-8409-9c09a9f80388'	System	21 Sep 2020 02:36:55
User entered '97.6'	System	21 Sep 2020 02:36:55

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T22:36:49', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'afe42b5b-df06-436e-8409-9c09a9f80388'	System	21 Sep 2020 02:36:55
User entered 'No (N)'	System	21 Sep 2020 02:36:55

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T22:36:51', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'afe42b5b-df06-436e-8409-9c09a9f80388'	System	21 Sep 2020 02:36:55
User entered '20 Sep 2020 22:36'	System	21 Sep 2020 02:36:55

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 5'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-21T13:17:24', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '6cbc706d-3d18-4661-b4c9-06f8d96c9d10'	System	21 Sep 2020 17:17:42
User entered 'Yes (Y)'	System	21 Sep 2020 17:17:42

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-21T13:17:32', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '6cbc706d-3d18-4661-b4c9-06f8d96c9d10'	System	21 Sep 2020 17:17:42
User entered '98.2'	System	21 Sep 2020 17:17:42

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-21T13:17:36', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '6cbc706d-3d18-4661-b4c9-06f8d96c9d10'	System	21 Sep 2020 17:17:42
User entered 'No (N)'	System	21 Sep 2020 17:17:42

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-21T13:17:39', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '6cbc706d-3d18-4661-b4c9-06f8d96c9d10'	System	21 Sep 2020 17:17:42
User entered '21 Sep 2020 13:17'	System	21 Sep 2020 17:17:42

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 6'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-23T08:05:14', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '5677d9dd-43c7-47f7-830d-a54c20f2463d'	System	23 Sep 2020 12:05:31
User entered 'Yes (Y)'	System	23 Sep 2020 12:05:31

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-23T08:05:19', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '5677d9dd-43c7-47f7-830d-a54c20f2463d'	System	23 Sep 2020 12:05:31
User entered '97.2'	System	23 Sep 2020 12:05:31

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-23T08:05:24', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '5677d9dd-43c7-47f7-830d-a54c20f2463d'	System	23 Sep 2020 12:05:31
User entered 'No (N)'	System	23 Sep 2020 12:05:31

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-23T08:05:27', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '5677d9dd-43c7-47f7-830d-a54c20f2463d'	System	23 Sep 2020 12:05:31
User entered '23 Sep 2020 08:05'	System	23 Sep 2020 12:05:31

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 7'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:27:55

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-24T10:22:13', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '61cdd88c-963e-42d6-a3e3-670a26437302'	System	24 Sep 2020 14:22:28
User entered 'Yes (Y)'	System	24 Sep 2020 14:22:28

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:27:55

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-24T10:22:18', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '61cdd88c-963e-42d6-a3e3-670a26437302'	System	24 Sep 2020 14:22:28
User entered '98.1'	System	24 Sep 2020 14:22:28

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-24T10:22:24', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '61cdd88c-963e-42d6-a3e3-670a26437302'	System	24 Sep 2020 14:22:28
User entered 'No (N)'	System	24 Sep 2020 14:22:28

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-24T10:22:27', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '61cdd88c-963e-42d6-a3e3-670a26437302'	System	24 Sep 2020 14:22:28
User entered '24 Sep 2020 10:22'	System	24 Sep 2020 14:22:28

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

[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 (0a34ae8fa3a903f1)', Time: '2020-09-17T10:26:45', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'ff5eed63-0b3f-4340-bce5-507284fe1da2'	System	17 Sep 2020 14:27:05
User entered 'None (1)'	System	17 Sep 2020 14:27:05

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-17T10:26:48', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'ff5eed63-0b3f-4340-bce5-507284fe1da2'	System	17 Sep 2020 14:27:05
User entered 'No (N)'	System	17 Sep 2020 14:27:05

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-17T10:26:51', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'ff5eed63-0b3f-4340-bce5-507284fe1da2'	System	17 Sep 2020 14:27:05
User entered 'No (N)'	System	17 Sep 2020 14:27:05

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

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 (0a34ae8fa3a903f1)', Time: '2020-09-17T10:26:56', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'ff5eed63-0b3f-4340-bce5-507284fe1da2'	System	17 Sep 2020 14:27:05
User entered 'None (1)'	System	17 Sep 2020 14:27:05

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-17T10:26:58', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'ff5eed63-0b3f-4340-bce5-507284fe1da2'	System	17 Sep 2020 14:27:05
User entered '17 Sep 2020 10:26'	System	17 Sep 2020 14:27:05

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 10:09'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:39'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

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 (0a34ae8fa3a903f1)', Time: '2020-09-18T09:51:02', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '2fde9541-8adc-4958-b907-bf750cc936aa'	System	18 Sep 2020 13:51:24
User entered 'None (1)'	System	18 Sep 2020 13:51:24

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-18T09:51:06', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '2fde9541-8adc-4958-b907-bf750cc936aa'	System	18 Sep 2020 13:51:24
User entered 'No (N)'	System	18 Sep 2020 13:51:24

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-18T09:51:10', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '2fde9541-8adc-4958-b907-bf750cc936aa'	System	18 Sep 2020 13:51:24
User entered 'No (N)'	System	18 Sep 2020 13:51:24

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

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 (0a34ae8fa3a903f1)', Time: '2020-09-18T09:51:16', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '2fde9541-8adc-4958-b907-bf750cc936aa'	System	18 Sep 2020 13:51:24
User entered 'None (1)'	System	18 Sep 2020 13:51:24

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-18T09:51:19', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '2fde9541-8adc-4958-b907-bf750cc936aa'	System	18 Sep 2020 13:51:24
User entered '18 Sep 2020 09:51'	System	18 Sep 2020 13:51:24

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 13:34'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 2'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:27:55

[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 (0a34ae8fa3a903f1)', Time: '2020-09-19T11:21:41', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'd72ba6db-6b46-4aa1-9319-c36038758183'	System	19 Sep 2020 15:21:55
User entered 'None (1)'	System	19 Sep 2020 15:21:55

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-19T11:21:46', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'd72ba6db-6b46-4aa1-9319-c36038758183'	System	19 Sep 2020 15:21:55
User entered 'No (N)'	System	19 Sep 2020 15:21:55

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-19T11:21:48', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'd72ba6db-6b46-4aa1-9319-c36038758183'	System	19 Sep 2020 15:21:55
User entered 'No (N)'	System	19 Sep 2020 15:21:55

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:27:55

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 (0a34ae8fa3a903f1)', Time: '2020-09-19T11:21:51', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'd72ba6db-6b46-4aa1-9319-c36038758183'	System	19 Sep 2020 15:21:55
User entered 'None (1)'	System	19 Sep 2020 15:21:55

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-19T11:21:53', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'd72ba6db-6b46-4aa1-9319-c36038758183'	System	19 Sep 2020 15:21:55
User entered '19 Sep 2020 11:21'	System	19 Sep 2020 15:21:55

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 3'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:27:55

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 (0a34ae8fa3a903f1)', Time: '2020-09-20T08:32:37', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f1a9762c-2352-47c9-a877-e3e2768cedb6'	System	20 Sep 2020 12:32:51
User entered 'None (1)'	System	20 Sep 2020 12:32:51

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T08:32:40', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f1a9762c-2352-47c9-a877-e3e2768cedb6'	System	20 Sep 2020 12:32:51
User entered 'No (N)'	System	20 Sep 2020 12:32:51

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T08:32:42', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f1a9762c-2352-47c9-a877-e3e2768cedb6'	System	20 Sep 2020 12:32:51
User entered 'No (N)'	System	20 Sep 2020 12:32:51

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:27:55

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 (0a34ae8fa3a903f1)', Time: '2020-09-20T08:32:44', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f1a9762c-2352-47c9-a877-e3e2768cedb6'	System	20 Sep 2020 12:32:51
User entered 'None (1)'	System	20 Sep 2020 12:32:51

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T08:32:46', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f1a9762c-2352-47c9-a877-e3e2768cedb6'	System	20 Sep 2020 12:32:51
User entered '20 Sep 2020 08:32'	System	20 Sep 2020 12:32:51

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 4'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:27:55

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 (0a34ae8fa3a903f1)', Time: '2020-09-20T22:36:57', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '61320c4c-c59f-4ada-92f2-9a0fa62b5861'	System	21 Sep 2020 02:37:14
User entered 'None (1)'	System	21 Sep 2020 02:37:14

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T22:37:01', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '61320c4c-c59f-4ada-92f2-9a0fa62b5861'	System	21 Sep 2020 02:37:14
User entered 'No (N)'	System	21 Sep 2020 02:37:14

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T22:37:05', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '61320c4c-c59f-4ada-92f2-9a0fa62b5861'	System	21 Sep 2020 02:37:14
User entered 'No (N)'	System	21 Sep 2020 02:37:14

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:27:55

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 (0a34ae8fa3a903f1)', Time: '2020-09-20T22:37:09', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '61320c4c-c59f-4ada-92f2-9a0fa62b5861'	System	21 Sep 2020 02:37:14
User entered 'None (1)'	System	21 Sep 2020 02:37:14

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T22:37:11', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '61320c4c-c59f-4ada-92f2-9a0fa62b5861'	System	21 Sep 2020 02:37:14
User entered '20 Sep 2020 22:37'	System	21 Sep 2020 02:37:14

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 5'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:27:55

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 (0a34ae8fa3a903f1)', Time: '2020-09-21T13:17:47', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'a4bf07a8-572a-442d-a486-b4d7487b7ebd'	System	21 Sep 2020 17:18:04
User entered 'None (1)'	System	21 Sep 2020 17:18:04

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-21T13:17:50', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'a4bf07a8-572a-442d-a486-b4d7487b7ebd'	System	21 Sep 2020 17:18:04
User entered 'No (N)'	System	21 Sep 2020 17:18:04

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-21T13:17:54', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'a4bf07a8-572a-442d-a486-b4d7487b7ebd'	System	21 Sep 2020 17:18:04
User entered 'No (N)'	System	21 Sep 2020 17:18:04

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:27:55

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 (0a34ae8fa3a903f1)', Time: '2020-09-21T13:17:56', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'a4bf07a8-572a-442d-a486-b4d7487b7ebd'	System	21 Sep 2020 17:18:04
User entered 'None (1)'	System	21 Sep 2020 17:18:04

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-21T13:17:59', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'a4bf07a8-572a-442d-a486-b4d7487b7ebd'	System	21 Sep 2020 17:18:04
User entered '21 Sep 2020 13:17'	System	21 Sep 2020 17:18:04

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 6'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:27:55

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 (0a34ae8fa3a903f1)', Time: '2020-09-23T08:05:31', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '5449c779-a854-46ad-ac30-7875c2dba939'	System	23 Sep 2020 12:05:42
User entered 'None (1)'	System	23 Sep 2020 12:05:42

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-23T08:05:34', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '5449c779-a854-46ad-ac30-7875c2dba939'	System	23 Sep 2020 12:05:42
User entered 'No (N)'	System	23 Sep 2020 12:05:42

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-23T08:05:36', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '5449c779-a854-46ad-ac30-7875c2dba939'	System	23 Sep 2020 12:05:42
User entered 'No (N)'	System	23 Sep 2020 12:05:42

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:27:55

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 (0a34ae8fa3a903f1)', Time: '2020-09-23T08:05:38', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '5449c779-a854-46ad-ac30-7875c2dba939'	System	23 Sep 2020 12:05:42
User entered 'None (1)'	System	23 Sep 2020 12:05:42

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-23T08:05:40', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '5449c779-a854-46ad-ac30-7875c2dba939'	System	23 Sep 2020 12:05:42
User entered '23 Sep 2020 08:05'	System	23 Sep 2020 12:05:42

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 7'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:27:55

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 (0a34ae8fa3a903f1)', Time: '2020-09-24T10:22:36', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'b75a777a-f31d-4005-b535-251ccfcfdc6f'	System	24 Sep 2020 14:22:53
User entered 'None (1)'	System	24 Sep 2020 14:22:53

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:27:55

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-24T10:22:40', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'b75a777a-f31d-4005-b535-251ccfcfdc6f'	System	24 Sep 2020 14:22:53
User entered 'No (N)'	System	24 Sep 2020 14:22:53

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-24T10:22:43', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'b75a777a-f31d-4005-b535-251ccfcfdc6f'	System	24 Sep 2020 14:22:53
User entered 'No (N)'	System	24 Sep 2020 14:22:53

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:27:55

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 (0a34ae8fa3a903f1)', Time: '2020-09-24T10:22:46', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'b75a777a-f31d-4005-b535-251ccfcfdc6f'	System	24 Sep 2020 14:22:53
User entered 'None (1)'	System	24 Sep 2020 14:22:53

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:27:55

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-24T10:22:49', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'b75a777a-f31d-4005-b535-251ccfcfdc6f' User entered '24 Sep 2020 10:22'	System	24 Sep 2020 14:22:53
	System	24 Sep 2020 14:22:53

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-17T10:27:05', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '47219a00-7814-4d90-aa4e-065b897aa00b'	System	17 Sep 2020 14:27:28
User entered 'None (0)'	System	17 Sep 2020 14:27:28

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-17T10:27:08', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '47219a00-7814-4d90-aa4e-065b897aa00b'	System	17 Sep 2020 14:27:28
User entered 'None (0)'	System	17 Sep 2020 14:27:28

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-17T10:27:10', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '47219a00-7814-4d90-aa4e-065b897aa00b'	System	17 Sep 2020 14:27:28
User entered 'None (0)'	System	17 Sep 2020 14:27:28

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-17T10:27:13', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '47219a00-7814-4d90-aa4e-065b897aa00b'	System	17 Sep 2020 14:27:28
User entered 'None (0)'	System	17 Sep 2020 14:27:28

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-17T10:27:15', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '47219a00-7814-4d90-aa4e-065b897aa00b'	System	17 Sep 2020 14:27:28
User entered 'None (0)'	System	17 Sep 2020 14:27:28

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-17T10:27:17', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '47219a00-7814-4d90-aa4e-065b897aa00b'	System	17 Sep 2020 14:27:28
User entered 'None (0)'	System	17 Sep 2020 14:27:28

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

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 (0a34ae8fa3a903f1)', Time: '2020-09-17T10:27:20', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '47219a00-7814-4d90-aa4e-065b897aa00b'	System	17 Sep 2020 14:27:28
User entered 'No (N)'	System	17 Sep 2020 14:27:28

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-17T10:27:22', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '47219a00-7814-4d90-aa4e-065b897aa00b'	System	17 Sep 2020 14:27:28
User entered '17 Sep 2020 10:27'	System	17 Sep 2020 14:27:28

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 10:09'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:39'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-18T09:51:27', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'cc960669-9533-49d6-b543-3c5b916db6fc'	System	18 Sep 2020 13:51:55
User entered 'None (0)'	System	18 Sep 2020 13:51:55

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-18T09:51:30', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'cc960669-9533-49d6-b543-3c5b916db6fc'	System	18 Sep 2020 13:51:55
User entered 'None (0)'	System	18 Sep 2020 13:51:55

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-18T09:51:33', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'cc960669-9533-49d6-b543-3c5b916db6fc'	System	18 Sep 2020 13:51:55
User entered 'None (0)'	System	18 Sep 2020 13:51:55

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-18T09:51:34', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'cc960669-9533-49d6-b543-3c5b916db6fc'	System	18 Sep 2020 13:51:55
User entered 'None (0)'	System	18 Sep 2020 13:51:55

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-18T09:51:37', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'cc960669-9533-49d6-b543-3c5b916db6fc'	System	18 Sep 2020 13:51:55
User entered 'None (0)'	System	18 Sep 2020 13:51:55

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-18T09:51:40', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'cc960669-9533-49d6-b543-3c5b916db6fc'	System	18 Sep 2020 13:51:55
User entered 'None (0)'	System	18 Sep 2020 13:51:55

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

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 (0a34ae8fa3a903f1)', Time: '2020-09-18T09:51:45', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'cc960669-9533-49d6-b543-3c5b916db6fc'	System	18 Sep 2020 13:51:55
User entered 'No (N)'	System	18 Sep 2020 13:51:55

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-18T09:51:47', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'cc960669-9533-49d6-b543-3c5b916db6fc'	System	18 Sep 2020 13:51:55
User entered '18 Sep 2020 09:51'	System	18 Sep 2020 13:51:55

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 13:34'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 2'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-19T11:22:11', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f524b88f-4875-41bf-a2d3-db5e6339bbe4'	System	19 Sep 2020 15:22:35
User entered 'None (0)'	System	19 Sep 2020 15:22:35

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-19T11:22:14', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f524b88f-4875-41bf-a2d3-db5e6339bbe4'	System	19 Sep 2020 15:22:35
User entered 'None (0)'	System	19 Sep 2020 15:22:35

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-19T11:22:16', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f524b88f-4875-41bf-a2d3-db5e6339bbe4'	System	19 Sep 2020 15:22:35
User entered 'None (0)'	System	19 Sep 2020 15:22:35

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-19T11:22:18', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f524b88f-4875-41bf-a2d3-db5e6339bbe4'	System	19 Sep 2020 15:22:35
User entered 'None (0)'	System	19 Sep 2020 15:22:35

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-19T11:22:20', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f524b88f-4875-41bf-a2d3-db5e6339bbe4'	System	19 Sep 2020 15:22:35
User entered 'None (0)'	System	19 Sep 2020 15:22:35

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-19T11:22:22', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f524b88f-4875-41bf-a2d3-db5e6339bbe4'	System	19 Sep 2020 15:22:35
User entered 'None (0)'	System	19 Sep 2020 15:22:35

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:55

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 (0a34ae8fa3a903f1)', Time: '2020-09-19T11:22:26', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f524b88f-4875-41bf-a2d3-db5e6339bbe4'	System	19 Sep 2020 15:22:35
User entered 'No (N)'	System	19 Sep 2020 15:22:35

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-19T11:22:32', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'f524b88f-4875-41bf-a2d3-db5e6339bbe4'	System	19 Sep 2020 15:22:35
User entered '19 Sep 2020 11:22'	System	19 Sep 2020 15:22:35

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 3'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T08:32:51', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '48b073a1-fc95-44c6-80f4-1a7201f52dc7'	System	20 Sep 2020 12:33:08
User entered 'None (0)'	System	20 Sep 2020 12:33:08

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T08:32:53', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '48b073a1-fc95-44c6-80f4-1a7201f52dc7'	System	20 Sep 2020 12:33:08
User entered 'None (0)'	System	20 Sep 2020 12:33:08

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T08:32:54', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '48b073a1-fc95-44c6-80f4-1a7201f52dc7'	System	20 Sep 2020 12:33:08
User entered 'None (0)'	System	20 Sep 2020 12:33:08

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T08:32:56', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '48b073a1-fc95-44c6-80f4-1a7201f52dc7'	System	20 Sep 2020 12:33:08
User entered 'None (0)'	System	20 Sep 2020 12:33:08

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T08:32:59', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '48b073a1-fc95-44c6-80f4-1a7201f52dc7'	System	20 Sep 2020 12:33:08
User entered 'None (0)'	System	20 Sep 2020 12:33:08

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T08:33:01', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '48b073a1-fc95-44c6-80f4-1a7201f52dc7'	System	20 Sep 2020 12:33:08
User entered 'None (0)'	System	20 Sep 2020 12:33:08

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:55

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 (0a34ae8fa3a903f1)', Time: '2020-09-20T08:33:03', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '48b073a1-fc95-44c6-80f4-1a7201f52dc7'	System	20 Sep 2020 12:33:08
User entered 'No (N)'	System	20 Sep 2020 12:33:08

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T08:33:06', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '48b073a1-fc95-44c6-80f4-1a7201f52dc7'	System	20 Sep 2020 12:33:08
User entered '20 Sep 2020 08:33'	System	20 Sep 2020 12:33:08

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 4'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T22:37:16', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '7e9b7ee5-ec58-4249-952f-e6788439a632'	System	21 Sep 2020 02:37:32
User entered 'None (0)'	System	21 Sep 2020 02:37:32

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T22:37:18', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '7e9b7ee5-ec58-4249-952f-e6788439a632'	System	21 Sep 2020 02:37:32
User entered 'None (0)'	System	21 Sep 2020 02:37:32

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T22:37:20', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '7e9b7ee5-ec58-4249-952f-e6788439a632'	System	21 Sep 2020 02:37:32
User entered 'None (0)'	System	21 Sep 2020 02:37:32

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T22:37:21', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '7e9b7ee5-ec58-4249-952f-e6788439a632'	System	21 Sep 2020 02:37:32
User entered 'None (0)'	System	21 Sep 2020 02:37:32

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T22:37:23', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '7e9b7ee5-ec58-4249-952f-e6788439a632'	System	21 Sep 2020 02:37:32
User entered 'None (0)'	System	21 Sep 2020 02:37:32

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T22:37:25', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '7e9b7ee5-ec58-4249-952f-e6788439a632'	System	21 Sep 2020 02:37:32
User entered 'None (0)'	System	21 Sep 2020 02:37:32

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:55

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 (0a34ae8fa3a903f1)', Time: '2020-09-20T22:37:28', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '7e9b7ee5-ec58-4249-952f-e6788439a632'	System	21 Sep 2020 02:37:32
User entered 'No (N)'	System	21 Sep 2020 02:37:32

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-20T22:37:30', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '7e9b7ee5-ec58-4249-952f-e6788439a632'	System	21 Sep 2020 02:37:32
User entered '20 Sep 2020 22:37'	System	21 Sep 2020 02:37:32

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 5'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-21T13:18:07', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '67607c99-a719-45ce-811f-e7eb5ad74848'	System	21 Sep 2020 17:18:25
User entered 'None (0)'	System	21 Sep 2020 17:18:25

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-21T13:18:09', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '67607c99-a719-45ce-811f-e7eb5ad74848'	System	21 Sep 2020 17:18:25
User entered 'None (0)'	System	21 Sep 2020 17:18:25

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-21T13:18:12', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '67607c99-a719-45ce-811f-e7eb5ad74848'	System	21 Sep 2020 17:18:25
User entered 'None (0)'	System	21 Sep 2020 17:18:25

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-21T13:18:14', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '67607c99-a719-45ce-811f-e7eb5ad74848'	System	21 Sep 2020 17:18:25
User entered 'None (0)'	System	21 Sep 2020 17:18:25

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-21T13:18:16', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '67607c99-a719-45ce-811f-e7eb5ad74848'	System	21 Sep 2020 17:18:25
User entered 'None (0)'	System	21 Sep 2020 17:18:25

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-21T13:18:17', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '67607c99-a719-45ce-811f-e7eb5ad74848'	System	21 Sep 2020 17:18:25
User entered 'None (0)'	System	21 Sep 2020 17:18:25

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:55

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 (0a34ae8fa3a903f1)', Time: '2020-09-21T13:18:19', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '67607c99-a719-45ce-811f-e7eb5ad74848'	System	21 Sep 2020 17:18:25
User entered 'No (N)'	System	21 Sep 2020 17:18:25

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-21T13:18:22', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '67607c99-a719-45ce-811f-e7eb5ad74848'	System	21 Sep 2020 17:18:25
User entered '21 Sep 2020 13:18'	System	21 Sep 2020 17:18:25

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 6'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-23T08:05:45', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c97522f1-d8a8-40a5-b654-aa0af7b8e782'	System	23 Sep 2020 12:06:00
User entered 'None (0)'	System	23 Sep 2020 12:06:00

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-23T08:05:47', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c97522f1-d8a8-40a5-b654-aa0af7b8e782'	System	23 Sep 2020 12:06:00
User entered 'None (0)'	System	23 Sep 2020 12:06:00

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-23T08:05:49', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c97522f1-d8a8-40a5-b654-aa0af7b8e782'	System	23 Sep 2020 12:06:00
User entered 'None (0)'	System	23 Sep 2020 12:06:00

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-23T08:05:50', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c97522f1-d8a8-40a5-b654-aa0af7b8e782'	System	23 Sep 2020 12:06:00
User entered 'None (0)'	System	23 Sep 2020 12:06:00

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-23T08:05:51', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c97522f1-d8a8-40a5-b654-aa0af7b8e782'	System	23 Sep 2020 12:06:00
User entered 'None (0)'	System	23 Sep 2020 12:06:00

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-23T08:05:53', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c97522f1-d8a8-40a5-b654-aa0af7b8e782'	System	23 Sep 2020 12:06:00
User entered 'None (0)'	System	23 Sep 2020 12:06:00

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:55

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 (0a34ae8fa3a903f1)', Time: '2020-09-23T08:05:56', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c97522f1-d8a8-40a5-b654-aa0af7b8e782'	System	23 Sep 2020 12:06:00
User entered 'No (N)'	System	23 Sep 2020 12:06:00

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-23T08:05:58', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'c97522f1-d8a8-40a5-b654-aa0af7b8e782'	System	23 Sep 2020 12:06:00
User entered '23 Sep 2020 08:05'	System	23 Sep 2020 12:06:00

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 13:59:44
User entered 'Day 7'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:55

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-24T10:22:58', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '2e7a8292-2dcf-450b-8750-154db16688f8'	System	24 Sep 2020 14:23:40
User entered 'None (0)'	System	24 Sep 2020 14:23:40

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:55

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-24T10:23:00', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '2e7a8292-2dcf-450b-8750-154db16688f8'	System	24 Sep 2020 14:23:40
User entered 'None (0)'	System	24 Sep 2020 14:23:40

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:55

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-24T10:23:02', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '2e7a8292-2dcf-450b-8750-154db16688f8'	System	24 Sep 2020 14:23:40
User entered 'None (0)'	System	24 Sep 2020 14:23:40

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:55

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-24T10:23:05', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '2e7a8292-2dcf-450b-8750-154db16688f8'	System	24 Sep 2020 14:23:40
User entered 'None (0)'	System	24 Sep 2020 14:23:40

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:55

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-24T10:23:07', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '2e7a8292-2dcf-450b-8750-154db16688f8'	System	24 Sep 2020 14:23:40
User entered 'None (0)'	System	24 Sep 2020 14:23:40

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:55

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-24T10:23:09', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '2e7a8292-2dcf-450b-8750-154db16688f8'	System	24 Sep 2020 14:23:40
User entered 'None (0)'	System	24 Sep 2020 14:23:40

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:55

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 (0a34ae8fa3a903f1)', Time: '2020-09-24T10:23:12', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '2e7a8292-2dcf-450b-8750-154db16688f8'	System	24 Sep 2020 14:23:40
User entered 'No (N)'	System	24 Sep 2020 14:23:40

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:55

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-09-24T10:23:18', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '2e7a8292-2dcf-450b-8750-154db16688f8'	System	24 Sep 2020 14:23:40
User entered '24 Sep 2020 10:23'	System	24 Sep 2020 14:23:40

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:55

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 13:59:44

US3432208

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:27:55

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 13:59:44

US3432208

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 14:21:14

US3432208

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:55

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 14:21:14

US3432208

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	24 Sep 2020 14:21:14

US3432208

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 14:21:14

US3432208

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 15:13:04

US3432208

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:55

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 15:13:04

US3432208

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 15:13:26

US3432208

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:55

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '1 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 15:13:26

US3432208

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Oct 2020 15:13:26

US3432208

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 15:13:26

US3432208

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 15:13:30

US3432208

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:55

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 15:13:30

US3432208

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 13:18:34

US3432208

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:55

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '8 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 13:18:34

US3432208

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	08 Oct 2020 13:18:34

US3432208

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 13:18:34

US3432208

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 13:20:44

US3432208

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:55

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 13:20:44

US3432208

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:27:55

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 14:51:45

US3432208

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 14:51:45

US3432208

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	13 Oct 2020 14:51:45

US3432208

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:27:55

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	13 Oct 2020 14:51:45

US3432208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:55

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 15:16:59

US3432208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:55

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 15:16:59

US3432208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 15:17:09
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	13 Oct 2020 15:17:09
User entered '8:22' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Oct 2020 15:17:09
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Oct 2020 15:16:59
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 15:16:59

US3432208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '13 Oct 2020 8:22'	System	13 Oct 2020 15:17:09
User entered empty.	System	13 Oct 2020 15:16:59

US3432208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:55

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.4' F	(b) (4), (b) (6)	13 Oct 2020 15:16:59

US3432208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:55

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	13 Oct 2020 15:16:59

US3432208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:55

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 15:16:59

US3432208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:55

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '97'	(b) (4), (b) (6)	13 Oct 2020 15:16:59

US3432208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:55

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	13 Oct 2020 15:16:59

US3432208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '14'	(b) (4), (b) (6)	13 Oct 2020 15:16:59

US3432208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:55

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	13 Oct 2020 15:16:59

US3432208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:55

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '139'	(b) (4), (b) (6)	13 Oct 2020 15:16:59

US3432208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:55

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Oct 2020 15:16:59

US3432208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:55

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '88'	(b) (4), (b) (6)	13 Oct 2020 15:16:59

US3432208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:27:55

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	13 Oct 2020 15:16:59

US3432208

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:27:55

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 15:17:18

US3432208

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:27:55

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 15:17:18

US3432208

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:27:55

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 17:11:00

US3432208

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:27:55

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 17:11:00

US3432208

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:27:55

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '8:56'	(b) (4), (b) (6)	13 Oct 2020 17:11:00

US3432208

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '13 Oct 2020 8:56'	System	13 Oct 2020 17:11:00

US3432208

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 15:17:26

US3432208

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:55

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 15:17:26

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 71'	System	20 Aug 2020 16:02:36

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[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 (0a34ae8fa3a903f1)', Time: '2020-10-29T06:54:17', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '3e186ded-79d8-415e-9a9e-217a153b0c23'	System	29 Oct 2020 10:55:09
User entered 'No (N)'	System	29 Oct 2020 10:55:09

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

Have you been exposed to someone with 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 (0a34ae8fa3a903f1)', Time: '2020-10-29T06:54:53', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '3e186ded-79d8-415e-9a9e-217a153b0c23'	System	29 Oct 2020 10:55:09
User entered 'No (N)'	System	29 Oct 2020 10:55:09

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-10-29T06:55:05', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: '3e186ded-79d8-415e-9a9e-217a153b0c23'	System	29 Oct 2020 10:55:09
User entered '29 Oct 2020 06:55:05'	System	29 Oct 2020 10:55:09

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:02:36
User entered '27 Oct 2020 00:01'	System	20 Aug 2020 16:02:36

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:02:36
User entered '31 Oct 2020 23:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:02:36
User entered 'Day 78'	System	20 Aug 2020 16:02:36

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[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 (0a34ae8fa3a903f1)', Time: '2020-11-03T00:02:01', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'eafb57e0-8029-4142-97b6-e0083cb6eb81'	System	03 Nov 2020 05:02:17
User entered 'No (N)'	System	03 Nov 2020 05:02:17

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

Have you been exposed to someone with 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 (0a34ae8fa3a903f1)', Time: '2020-11-03T00:02:11', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'eafb57e0-8029-4142-97b6-e0083cb6eb81'	System	03 Nov 2020 05:02:17
User entered 'No (N)'	System	03 Nov 2020 05:02:17

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0a34ae8fa3a903f1)', Time: '2020-11-03T00:02:15', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'eafb57e0-8029-4142-97b6-e0083cb6eb81'	System	03 Nov 2020 05:02:17
User entered '03 Nov 2020 00:02:15'	System	03 Nov 2020 05:02:17

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:02:36
User entered '03 Nov 2020 00:01'	System	20 Aug 2020 16:02:36

US3432208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	20 Aug 2020 16:02:36
User entered '07 Nov 2020 23:59'	System	20 Aug 2020 16:02:36

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '17 Oct 2020 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '21 Oct 2020 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '24 Oct 2020 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '28 Oct 2020 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '31 Oct 2020 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '04 Nov 2020 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '07 Nov 2020 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '11 Nov 2020 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '14 Nov 2020 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '18 Nov 2020 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[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 (4c534fb9ff11f482)', Time: '2020-11-24T13:18:55', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'e3014c75-8f0a-4339-9fa0-b08ab359f604'	System	24 Nov 2020 18:19:12
User entered 'No (N)'	System	24 Nov 2020 18:19:12

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

Have you been exposed to someone with 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 (4c534fb9ff11f482)', Time: '2020-11-24T13:19:02', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'e3014c75-8f0a-4339-9fa0-b08ab359f604'	System	24 Nov 2020 18:19:12
User entered 'No (N)'	System	24 Nov 2020 18:19:12

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (4c534fb9ff11f482)', Time: '2020-11-24T13:19:07', User OID: 'PatientReportedOutcome (US3432208)', ODM File OID: 'e3014c75-8f0a-4339-9fa0-b08ab359f604'	System	24 Nov 2020 18:19:12
User entered '24 Nov 2020 13:19:07'	System	24 Nov 2020 18:19:12

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '22 Oct 2022 00:01'	System	19 Nov 2020 23:34:34

US3432208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:27:55

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:34:34
Amendment Manager: User entered '26 Oct 2022 23:59'	System	19 Nov 2020 23:34:34

US3432208

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:55

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kathleen Garvey (b) (4) (b) (4)	12 Nov 2020 17:20:40

US3432208

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:55

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '12 Nov 2020'	Kathleen Garvey (b) (4) (b) (4)	12 Nov 2020 17:20:40

US3432208

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:55

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Kathleen Garvey (b) (4) (b) (4)	12 Nov 2020 17:20:40

US3432208

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:27:55

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Kathleen Garvey (b) (4) (b) (4)	12 Nov 2020 17:20:40

US3432208

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Kathleen Garvey (b) (4) (b) (4)	12 Nov 2020 17:20:46

US3432208

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:27:55

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Nov 2020 17:20:46

US3432208

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:27:55

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:32:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 14:20:09

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:32:16
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:01:51
User entered 'USA-US078-2020-mRNA-1273-P301000004'	System	14 Oct 2020 12:01:46
User entered 'New'	(b) (4), (b) (6)	14 Oct 2020 12:01:46

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:32:19
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Spine and neck deformities, PT: Spinal stenosis, LLT: Spinal stenosis - version MedDRA\\23.0.	Coder Import (b) (4)	13 Oct 2020 14:31:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	13 Oct 2020 14:31:32
Data point term sent to Coder	System	13 Oct 2020 14:30:42
User entered 'Spinal Stenosis'	(b) (4), (b) (6)	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:32:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:07
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:08
User closed query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No. ' (Site from Safety). Query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No. ' answered with 'this was entered incorrectly' (Site from Safety).	(b) (4), (b) (6)	16 Oct 2020 15:08:01
User entered 'No (N)' reason for change: Data Entry Error	Monica Feeley (b) (4)	15 Oct 2020 15:46:25
User opened query 'PV Query Urgent: Is this an event of positive Covid-19? If yes, please update event term to Covid-19 and add results under Covid Diagnostic Test in the Covid-19 Assessments tab. If no, please change answer to No. ' (Site from Safety). User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Oct 2020 12:00:16
	(b) (4), (b) (6)	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:10
User entered '07 Sep 2020'	(b) (4), (b) (6)	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:12
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:14
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:16
User entered '05 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:17
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

Severity

Audit	User	Time (GMT)
User closed query 'PV Query: As event resulted in hospitalization, please confirm intensity of grade 3 and consider updating to grade 4.' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 00:19:29
Query 'PV Query: As event resulted in hospitalization, please confirm intensity of grade 3 and consider updating to grade 4.' answered with 'grade for is life threatening, of which, this was not' (Site from Safety).	Monica Feeley (b) (4)	20 Nov 2020 19:46:16
User opened query 'PV Query: As event resulted in hospitalization, please confirm intensity of grade 3 and consider updating to grade 4.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:59:22
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:20
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:25
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:28
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:30
User entered '1'	(b) (4), (b) (6)	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:31
User entered '02 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:34
User entered '05 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:35
User entered 'No (N)'	(b) (4), (b) (6)	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:38
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:39
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:41
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:43
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:56:44
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:57:18
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

Action taken with investigational product

Audit	User	Time (GMT)
User closed query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If dose is delayed, please update action to Dose delayed. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 20:50:44
Query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If dose is delayed, please update action to Dose delayed. If patient will not be receiving further IP doses, please update action taken to withdrawn.' answered with 'There was no action taken. received both first and second dose within window' (Site from Safety).	Monica Feeley (b) (4)	28 Oct 2020 16:14:19
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:57:23
User opened query 'PV Query: Please clarify action taken with IP with regards to next scheduled vaccine administration. If dose is delayed, please update action to Dose delayed. If patient will not be receiving further IP doses, please update action taken to withdrawn.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 14:28:39
User entered 'None (NONE)'	(b) (4), (b) (6)	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

None

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = None. However, it appears that the subject had a Cervical Discectomy + Fusion as treatment for this AE. Please review and update applicable details accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 16:55:46
Query 'Per DM CLR: Other Action Taken = None. However, it appears that the subject had a Cervical Discectomy + Fusion as treatment for this AE. Please review and update applicable details accordingly. Otherwise, clarify.' answered with 'updated' (Site from DM).	Monica Feeley (b) (4)	30 Oct 2020 14:14:04
DataPoint Un-verified.	Monica Feeley (b) (4)	30 Oct 2020 14:13:57
User entered '0' reason for change: Per Query Resolution	Monica Feeley (b) (4)	30 Oct 2020 14:13:57
User opened query 'Per DM CLR: Other Action Taken = None. However, it appears that the subject had a Cervical Discectomy + Fusion as treatment for this AE. Please review and update applicable details accordingly. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 20:40:35
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:03
User entered '1'	(b) (4), (b) (6)	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Monica Feeley (b) (4)	30 Oct 2020 14:13:57
User entered '1' reason for change: New Information	(b) (4)	
	Monica Feeley (b) (4)	30 Oct 2020 14:13:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 14:58:04
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Monica Feeley (b) (4)	30 Oct 2020 14:13:57
User entered '1' reason for change: New Information	(b) (4)	
	Monica Feeley (b) (4)	30 Oct 2020 14:13:57
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 14:58:06
User entered '0'	(b) (4), (b) (6)	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:10
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Monica Feeley (b) (4)	20 Nov 2020 19:48:34
User entered 'AN MRI OF C-SPINE ON 9/7/2020 REVEALED CANAL STENOSIS AT C5-7; HE UNDERWENT AN ANTERIOR CERVICAL DISECTOMY + FUSION ON 10/2/2020; POST OP COURSE UNREMARKABLE AND DISCHARGED ON 10/5/2020. Participant reported this to site on 13OCT2020 during their scheduled visit 3.' reason for change: Per Query Resolution	Monica Feeley (b) (4)	20 Nov 2020 19:48:34
User closed query 'PV Query: Please provide treatment medications given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 17:58:32
Query 'PV Query: Please provide treatment medications given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'see con med' (Site from Safety).	Monica Feeley (b) (4)	10 Nov 2020 21:43:42
User opened query 'PV Query: Please provide treatment medications given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Nov 2020 12:39:06
User closed query 'Per DM CLR: SAE narrative indicates that the subject underwent MRI of Cervical spine and had Cervical Discectomy + Fusion. However, there are no corresponding Concomitant Procedures record that match these information. Please update to record the procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 16:55:24

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment medications given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	02 Nov 2020 13:52:45
Query 'Per DM CLR: SAE narrative indicates that the subject underwent MRI of Cervical spine and had Cervical Discectomy + Fusion. However, there are no corresponding Concomitant Procedures record that match these information. Please update to record the procedures as appropriate. Otherwise, clarify.' answered with 'please see con procedures updates' (Site from DM).	Monica Feeley (b) (4)	30 Oct 2020 14:27:18
Query 'PV Query: Please provide treatment medications given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'please see con medications for updated' (Site from Safety).	Monica Feeley (b) (4)	30 Oct 2020 14:26:58
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 20:50:11
User opened query 'Per DM CLR: SAE narrative indicates that the subject underwent MRI of Cervical spine and had Cervical Discectomy + Fusion. However, there are no corresponding Concomitant Procedures record that match these information. Please update to record the procedures as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 20:41:01
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with '05OCT2020 COVID-19 test negative' (Site from Safety).	Monica Feeley (b) (4)	28 Oct 2020 16:19:51
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:15

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment medications given for the event. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 14:28:26
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 14:28:12
User entered 'An MRI of c-Spine on 9/7/2020 revealed canal stenosis at C5-7; he underwent an anterior cervical disectomy + fusion on 10/2/2020; post op course unremarkable and discharged on 10/5/2020'	(b) (4), (b) (6)	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Oct 2020 14:30:36

US3432208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:27:55

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	13 Oct 2020 14:30:36

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:27:55

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User closed query 'Per ETRTR: Please confirm SAE "Spinal Stenosis" did not required ConMed, otherwise update accordingly, thanks.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 22:47:23
Query 'Per ETRTR: Please confirm SAE "Spinal Stenosis" did not required ConMed, otherwise update accordingly, thanks.' answered with 'Updated' (Site from CRA).	Alexander Mills (b) (4)	10 Nov 2020 22:15:28
DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 17:35:14
User opened query 'Per ETRTR: Please confirm SAE "Spinal Stenosis" did not required ConMed, otherwise update accordingly, thanks.' (Site from CRA).	(b) (4), (b) (6)	15 Oct 2020 21:59:03
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:24:00

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE BESILATE, PRODUCTSYNONYM: NORVASC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 17:26:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 17:26:31
Data point term sent to Coder	System	20 Aug 2020 17:26:04
User entered 'Norvasc'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:25:59

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:25:59

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:55

[Indication](#)

Audit	User	Time (GMT)
User entered 'Hypertension'	Phoebe Cunningham	20 Aug 2020 17:25:59
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:25:59

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Phoebe Cunningham	20 Aug 2020 17:25:59
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:25:59

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:25:59

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:25:59

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:25:59

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:25:59

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:48:12
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Phoebe Cunningham	20 Aug 2020 17:30:57
answered with 'per protocol' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 17:25:59
User entered 'un UNK 2000'	Phoebe Cunningham	20 Aug 2020 17:25:59
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:25:59

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:25:59

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:25:59

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:25:59

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 17:25:59

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 17:25:59

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 17:25:59

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 17:28:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 17:28:24
Data point term sent to Coder	System	20 Aug 2020 17:27:05
User entered 'Metformin'	Phoebe Cunningham	20 Aug 2020 17:26:42
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:26:42

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:55

[Indication](#)

Audit	User	Time (GMT)
User entered 'Type II Diabetes'	Phoebe Cunningham	20 Aug 2020 17:26:42
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '500'	Phoebe Cunningham	20 Aug 2020 17:26:42
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Phoebe Cunningham	20 Aug 2020 17:26:42
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:26:42

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Phoebe Cunningham	20 Aug 2020 17:26:42
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:26:42

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Phoebe Cunningham	20 Aug 2020 17:26:42
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:26:42

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:48:12
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Phoebe Cunningham	20 Aug 2020 17:30:50
answered with 'per protocol' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 17:26:42
User entered 'un UNK 2018'	Phoebe Cunningham	20 Aug 2020 17:26:42
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:26:42

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:26:42

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:26:42

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:26:42

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Aug 2020 17:26:42

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 17:26:42

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 17:26:42

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 17:30:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 17:30:31
Data point term sent to Coder	System	20 Aug 2020 17:29:15
User entered 'Sertraline'	Phoebe Cunningham	20 Aug 2020 17:28:52
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:28:52

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:55

[Indication](#)

Audit	User	Time (GMT)
User entered 'Depression'	Phoebe Cunningham	20 Aug 2020 17:28:52
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 07:41:14
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'Dose is reported as reported by participant' (Site from DM).	Megan Powell (b) (4) (b) (4)	21 Oct 2020 23:12:21
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	01 Oct 2020 09:03:56
User entered '10'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:28:52

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Phoebe Cunningham	20 Aug 2020 17:28:52
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:28:52

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Phoebe Cunningham	20 Aug 2020 17:28:52
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:28:52

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:28:52

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:28:52

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:48:12
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Phoebe Cunningham	20 Aug 2020 17:30:43
answered with 'per protocol' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 17:28:52
User entered 'un UNK 2015'	Phoebe Cunningham	20 Aug 2020 17:28:52
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:28:52

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:28:52

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:28:52

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:28:52

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 17:28:52

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 17:28:52

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 17:28:52

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:55

[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: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 17:32:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 17:32:25
Data point term sent to Coder	System	20 Aug 2020 17:31:24
User entered 'Omeprazole'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:30:25

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:30:25

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:55

[Indication](#)

Audit	User	Time (GMT)
User entered 'Dyspepsia'	Phoebe Cunningham	20 Aug 2020 17:30:25
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '40'	Phoebe Cunningham	20 Aug 2020 17:30:25
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Phoebe Cunningham	20 Aug 2020 17:30:25
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:55

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:30:25

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
User entered 'other (OTHER)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:30:25

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered 'twice a day and as needed'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:30:25

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Phoebe Cunningham	20 Aug 2020 17:30:25
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:55

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:30:25

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:48:12
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Phoebe Cunningham	20 Aug 2020 17:30:35
answered with 'per protocol' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	20 Aug 2020 17:30:25
User entered 'un UNK 2017'	Phoebe Cunningham	20 Aug 2020 17:30:25
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:30:25

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:30:25

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	20 Aug 2020 17:30:25

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Phoebe Cunningham (b) (4)	20 Aug 2020 17:30:25

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 17:30:25

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 17:30:25

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 17:30:25

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:18
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 21:51:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 21:51:46
Data point term sent to Coder	System	10 Nov 2020 21:51:26
User entered 'Lorazepam'	Alexander Mills (b) (4)	10 Nov 2020 21:51:10
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:24
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 21:51:10

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:55

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:22
User entered 'Anxiety'	Alexander Mills (b) (4)	10 Nov 2020 21:51:10
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:26
User entered '0.5'	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 21:51:10

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:28
User entered 'mg (mg)'	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 21:51:10

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:55

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:30
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 21:51:10
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:32
User entered 'as needed (PRN)'	Alexander Mills (b) (4)	10 Nov 2020 21:51:10
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:41
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:39
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:34
User entered empty.	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 21:51:10

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:44
User entered 'Oral (ORAL)'	Alexander Mills (b) (4)	10 Nov 2020 21:51:10
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:55

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:47
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 21:51:10
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:49
User entered '5 Oct 2020'	Alexander Mills (b) (4)	10 Nov 2020 21:51:10

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:51
User entered '0'	Alexander Mills (b) (4)	10 Nov 2020 21:51:10
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:54
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 21:51:10
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:07:59
User entered '6 Oct 2020'	Alexander Mills (b) (4)	10 Nov 2020 21:51:10
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:08:02
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 21:51:10
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:51:10

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:51:10

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:51:10

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:50
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 23:51:51
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 23:51:51
Data point term sent to Coder	System	10 Nov 2020 21:58:42
User entered 'Hydromorphone'	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 21:57:48

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:53
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 21:57:48
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:55

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:55
User entered 'Pain from spine surgery'	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 21:57:48

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:49:38
Query 'Hydromorphone: EMR: 0.2-0.4mg: IV: 03-04Oct20, please add new entry, since dates are different' canceled (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 18:48:15
Query 'Per source EMR: dose is 0.5mg only on 2Oct20, please review and edit. ' canceled (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 18:48:07
User opened query 'Hydromorphone: EMR: 0.2-0.4mg: IV: 03-04Oct20, please add new entry, since dates are different' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 18:45:05
User opened query 'Per source EMR: dose is 0.5mg only on 2Oct20, please review and edit. ' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 18:41:50
User entered '0.2-0.5'	Alexander Mills (b) (4)	10 Nov 2020 21:57:48

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:40:59
User entered 'mg (mg)'	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 21:57:48

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:49:40
User entered empty.	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 21:57:48

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:49:41
User entered 'as needed (PRN)'	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 21:57:48

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:49:43
User entered empty.	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 21:57:48

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:49:45
User entered 'Intravenous (INTRAVENOUS)'	Alexander Mills (b) (4)	10 Nov 2020 21:57:48
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:55

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:49:47
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 21:57:48
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
User entered '2 Oct 2020'	Alexander Mills (b) (4)	10 Nov 2020 21:57:48
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 21:57:48

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 21:57:48

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '2 Oct 2020'	Alexander Mills (b) (4)	10 Nov 2020 21:57:48
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 21:57:48

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:57:48

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:57:48

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:57:48

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:51:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Nov 2020 07:54:55
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 07:54:55
Data point term sent to Coder	System	10 Nov 2020 21:58:43
Data point term sent to Coder	System	10 Nov 2020 21:54:31
User entered 'Hydromorphone'	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 21:53:47

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:51:37
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 21:53:47
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:55

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:51:39
User entered 'Pain from spine surgery'	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 21:53:47

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:51:41
User entered '2-4' reason for change: Data Entry Error	Alexander Mills (b) (4)	10 Nov 2020 21:58:36
User entered '0.2-0.5'	Alexander Mills (b) (4)	10 Nov 2020 21:53:47

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:51:44
User entered 'mg (mg)'	Alexander Mills (b) (4)	10 Nov 2020 21:53:47
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:51:49
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 21:53:47
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:51:50
User entered 'other (OTHER)' reason for change:	Alexander Mills (b) (4)	10 Nov 2020 21:58:36
Data Entry Error	(b) (4)	
User entered 'as needed (PRN)'	Alexander Mills (b) (4)	10 Nov 2020 21:53:47
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:55:03
User entered 'Every 3 hours' reason for change: DataEntry Error	Alexander Mills (b) (4)	10 Nov 2020 21:58:36
User entered empty.	(b) (4)	
	Alexander Mills (b) (4)	10 Nov 2020 21:53:47
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:55:21
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Alexander Mills (b) (4)	10 Nov 2020 21:58:36
User entered 'Intravenous (INTRAVENOUS)'	Alexander Mills (b) (4)	10 Nov 2020 21:53:47

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:55

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:55:25
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 21:53:47
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:55:29
User entered '4 Oct 2020' reason for change: Data Entry Error	Alexander Mills (b) (4)	10 Nov 2020 21:58:36
User entered '2 Oct 2020'	Alexander Mills (b) (4)	10 Nov 2020 21:53:47

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:55:32
User entered '0'	Alexander Mills (b) (4)	10 Nov 2020 21:53:47
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:55:34
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 21:53:47
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:55

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:55:38
User entered '6 Oct 2020' reason for change: Data Entry Error	Alexander Mills (b) (4)	10 Nov 2020 21:58:36
User entered '2 Oct 2020'	Alexander Mills (b) (4)	10 Nov 2020 21:53:47

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:55:40
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 21:53:47
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:53:47

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:53:47

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 21:53:47

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:56:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 15:01:32
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Nov 2020 15:01:32
Data point term sent to Coder	System	10 Nov 2020 22:00:47
User entered 'Oxycodone'	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 22:00:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:56:19
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 22:00:12
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:27:55

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:56:21
User entered 'Pain from spine surgery'	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 22:00:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:56:25
User entered '5-10'	Alexander Mills (b) (4)	10 Nov 2020 22:00:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:56:29
User entered 'mg (mg)'	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 22:00:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:27:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:56:44
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:00:12
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:56:50
User entered 'as needed (PRN)'	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 22:00:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:03
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:00:12
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:07
User entered 'Oral (ORAL)'	Alexander Mills (b) (4)	10 Nov 2020 22:00:12
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:27:55

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:11
User entered empty.	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 22:00:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:16
User entered '2 Oct 2020'	Alexander Mills (b) (4)	10 Nov 2020 22:00:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:25
User entered '0'	Alexander Mills (b) (4)	10 Nov 2020 22:00:12
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:27
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 22:00:12
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:27:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:30
User entered '4 Oct 2020'	Alexander Mills (b) (4)	10 Nov 2020 22:00:12
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:57:32
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 22:00:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:00:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:00:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:00:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:28:35
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:17:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:17:42
Data point term sent to Coder	System	10 Nov 2020 22:01:49
User entered 'Zofran'	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 22:01:33

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:28:40
User entered 'No (N)'	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 22:01:33

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:27:55

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:28:45
User entered 'Nausea'	Alexander Mills (b) (4)	10 Nov 2020 22:01:33
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:28:49
User entered '4'	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 22:01:33

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:29:44
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 22:01:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 22:01:48
User entered 'mg (mg)' reason for change: Data Entry Error	Alexander Mills (b) (4)	10 Nov 2020 22:01:48
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 22:01:33
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:01:33

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:27:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:29:49
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:01:33
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
Query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please review if the alternative is appropriate and consider updating the frequency to the available equivalent rather than Other. Thank you.' answered with 'taken every 6 hours is not an option ' (Site from DM).	Monica Feeley (b) (4)	20 Nov 2020 20:03:57
User opened query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please review if the alternative is appropriate and consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 14:05:32
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:29:52
User entered 'other (OTHER)'	Alexander Mills (b) (4)	10 Nov 2020 22:01:33

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:29:56
User entered 'Every 6 hours'	Alexander Mills (b) (4)	10 Nov 2020 22:01:33
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:29:59
User entered 'Oral (ORAL)'	Alexander Mills (b) (4)	10 Nov 2020 22:01:33
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:27:55

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:30:05
User entered empty.	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 22:01:33

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:30:09
User entered '2 Oct 2020'	Alexander Mills (b) (4)	10 Nov 2020 22:01:33

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:30:14
User entered '0'	Alexander Mills (b) (4)	10 Nov 2020 22:01:33

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:32:46
User closed query 'Source EMR: stop date is 06Oct20, please review and edit' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 22:32:44
Query 'Source EMR: stop date is 06Oct20, please review and edit' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	20 Nov 2020 20:04:18
User entered 'No (N)' reason for change: Data Entry Error	Monica Feeley (b) (4)	20 Nov 2020 20:04:14
User opened query 'Source EMR: stop date is 06Oct20, please review and edit' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 19:00:56
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 19:00:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:30:18
User entered 'Yes (Y)'	Alexander Mills (b) (4)	10 Nov 2020 22:01:33

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:27:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:32:47
DataPoint Un-verified.	Monica Feeley (b) (4)	20 Nov 2020 20:04:14
User entered '06 Oct 2020' reason for change: Data Entry Error	Monica Feeley (b) (4)	20 Nov 2020 20:04:14
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:30:21
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:01:33

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:30:25
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 22:01:33
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:01:33

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:01:33

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 26 Nov 2020 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:01:33

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:58:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:19:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:19:41
Data point term sent to Coder	System	10 Nov 2020 22:03:56
User entered 'Zofran'	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 22:03:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:58:35
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 22:03:12
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:27:55

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:58:38
User entered 'Nausea'	Alexander Mills (b) (4)	10 Nov 2020 22:03:12
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:58:40
User entered '2'	Alexander Mills (b) (4)	10 Nov 2020 22:03:12
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:58:42
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 22:03:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 22:03:22
User entered 'mg (mg)' reason for change: Data Entry Error	Alexander Mills (b) (4)	10 Nov 2020 22:03:22
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 22:03:12
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:03:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:27:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:58:44
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:03:12
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
Query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please review if the alternative is appropriate and consider updating the frequency to the available equivalent rather than Other. Thank you.' answered with 'this is every 6 hours?' (Site from DM).	Monica Feeley (b) (4)	20 Nov 2020 20:04:38
User opened query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please review if the alternative is appropriate and consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 14:05:40
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:58:48
User entered 'other (OTHER)'	Alexander Mills (b) (4)	10 Nov 2020 22:03:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:58:50
User entered 'Every 6 hours'	Alexander Mills (b) (4)	10 Nov 2020 22:03:12
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:58:53
User entered 'Intravenous (INTRAVENOUS)'	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 22:03:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:27:55

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:58:56
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:03:12
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:58:58
User entered '2 Oct 2020'	Alexander Mills (b) (4)	10 Nov 2020 22:03:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:59:00
User entered '0'	Alexander Mills (b) (4)	10 Nov 2020 22:03:12
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:59:03
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 22:03:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:27:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:59:06
User entered '6 Oct 2020'	Alexander Mills (b) (4)	10 Nov 2020 22:03:12
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 18:59:10
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 22:03:12
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:03:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:03:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 26 Nov 2020 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:03:12

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:27:55

[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) (b) (4)	20 Nov 2020 20:08:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Nov 2020 20:08:03
Data point term sent to Coder	System	20 Nov 2020 20:07:16
Coding entries removed.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 20:06:26
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:12:26
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) (b) (4)	10 Nov 2020 22:24:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:24:42
Data point term sent to Coder	System	10 Nov 2020 22:08:06
User entered 'Acetaminophen'	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 22:07:51

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:12:30
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 22:07:51
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:27:55

[Indication](#)

Audit	User	Time (GMT)
Query 'please revise to "pain from surgery for Spinal stenosis: or con-procedure: : pain from DISCECTOMY ANTERIOR CERVICAL SPINE FUSION procedure.' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 20:06:37
User entered 'pain from surgery for spinal stenosis' reason for change: Data Entry Error	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 20:06:26
User opened query 'please revise to "pain from surgery for Spinal stenosis: or con-procedure: : pain from DISCECTOMY ANTERIOR CERVICAL SPINE FUSION procedure.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 16:16:25
User entered 'Pain from spine surgery'	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 22:07:51

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:16:28
User entered '650'	Alexander Mills (b) (4)	10 Nov 2020 22:07:51

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:16:30
User entered 'mg (mg)'	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 22:07:51

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:27:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:16:33
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:07:51
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
Query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please review if the alternative is appropriate and consider updating the frequency to the available equivalent rather than Other. Thank you.' answered with 'every 6 hours??' (Site from DM).	Monica Feeley (b) (4)	20 Nov 2020 20:06:08
User opened query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please review if the alternative is appropriate and consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 14:06:01
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:16:35
User entered 'other (OTHER)'	Alexander Mills (b) (4)	10 Nov 2020 22:07:51

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:16:41
User entered 'Every 6 hours'	Alexander Mills (b) (4)	10 Nov 2020 22:07:51
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:16:42
User entered 'Oral (ORAL)'	Alexander Mills (b) (4)	10 Nov 2020 22:07:51
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:27:55

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:16:46
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:07:51
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:16:47
User entered '2 Oct 2020'	Alexander Mills (b) (4)	10 Nov 2020 22:07:51

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:16:50
User entered '0'	Alexander Mills (b) (4)	10 Nov 2020 22:07:51
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:16:51
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 22:07:51
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:27:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:09:48
Query 'Stop date not mentioned in hospital records. How was the stop date noted? Per DS pg 11: update on 10Nov20: subject was not taking this? Please check and update.' canceled (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 19:09:46
User opened query 'Stop date not mentioned in hospital records. How was the stop date noted? Per DS pg 11: update on 10Nov20: subject was not taking this? Please check and update.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 16:22:29
User entered '6 Oct 2020'	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 22:07:51

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:16:54
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 22:07:51

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:07:51

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:07:51

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 26 Nov 2020 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:07:51

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: BISACODYL, PRODUCTSYNONYM: DULCOLAX [BISACODYL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 11:55:56
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 11:55:56
Data point term sent to Coder Coding entries removed.	System Monica Feeley (b) (4)	20 Nov 2020 20:06:11 20 Nov 2020 20:05:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:10:24
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: BISACODYL, PRODUCTSYNONYM: DULCOLAX [BISACODYL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:10:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:10:44
Data point term sent to Coder User entered 'Dulcolax'	System Alexander Mills (b) (4) (b) (4)	10 Nov 2020 22:10:09 10 Nov 2020 22:09:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:10:28
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 22:09:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:27:55

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:10:32
User entered 'Constipation'	Alexander Mills (b) (4)	10 Nov 2020 22:09:31
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:10:35
User entered '10'	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 22:09:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:10:38
User entered 'mg (mg)'	Alexander Mills (b) (4)	10 Nov 2020 22:09:31
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:27:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:10:40
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:09:31
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:10:43
User entered 'as needed (PRN)'	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 22:09:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:10:47
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:09:31
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:34:40
User closed query 'per source EMR: route is Rectal for suppository' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 22:34:38
Query 'per source EMR: route is Rectal for suppository' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	20 Nov 2020 20:05:50
User entered 'Rectal (RECTAL)' reason for change: Data Entry Error	Monica Feeley (b) (4)	20 Nov 2020 20:05:45
User opened query 'per source EMR: route is Rectal for suppository' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 19:11:57
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 19:11:01
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:10:50
User entered 'Oral (ORAL)'	Alexander Mills (b) (4)	10 Nov 2020 22:09:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:27:55

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:10:54
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:09:31
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:13:07
User entered '2 Oct 2020'	Alexander Mills (b) (4)	10 Nov 2020 22:09:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:13:15
User entered '0'	Alexander Mills (b) (4)	10 Nov 2020 22:09:31
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:13:19
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 22:09:31
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:27:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:13:23
User entered '6 Oct 2020'	Alexander Mills (b) (4)	10 Nov 2020 22:09:31
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:13:25
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 22:09:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:09:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:09:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 26 Nov 2020 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:09:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:32:20
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: SOFTENERS, EMOLLIENTS, PRODUCT: DOCUSATE SODIUM, PRODUCTSYNONYM: COLACE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:11:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 22:11:45
Data point term sent to Coder	System	10 Nov 2020 22:11:10
User entered 'Colace'	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 22:10:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:32:23
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 22:10:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 22:10:37
User entered 'No (N)' reason for change: Data Entry Error	Alexander Mills (b) (4)	10 Nov 2020 22:10:37
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 22:10:31
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:10:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:27:55

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:32:28
User entered 'Constipation'	Alexander Mills (b) (4)	10 Nov 2020 22:10:31
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:32:31
User entered '100'	Alexander Mills (b) (4)	10 Nov 2020 22:10:31
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:32:34
User entered 'mg (mg)'	Alexander Mills (b) (4)	10 Nov 2020 22:10:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:27:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:32:36
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:10:31
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:32:38
User entered 'as needed (PRN)'	Alexander Mills (b) (4)	10 Nov 2020 22:10:31
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:32:40
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:10:31
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:32:47
User entered 'Oral (ORAL)'	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 22:10:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:27:55

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:32:50
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:10:31
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:32:52
User entered '2 Oct 2020'	Alexander Mills (b) (4)	10 Nov 2020 22:10:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:32:56
User entered '0'	Alexander Mills (b) (4)	10 Nov 2020 22:10:31
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:33:00
User entered 'Yes (Y)'	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 22:10:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:27:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:33:02
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:10:31
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:33:07
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 22:10:31
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:10:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:10:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 26 Nov 2020 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:10:31

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 06:29:51
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Nov 2020 06:29:51
Data point term sent to Coder	System	20 Nov 2020 20:08:16
Coding entries removed.	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 20:07:50
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:23:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE;PARACETAMOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 23:51:50
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 23:51:50
Data point term sent to Coder	System	10 Nov 2020 22:13:12
User entered 'Hydrocodone/ Acetaminophen'	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 22:12:14

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:23:19
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 22:12:14

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:27:55

[Indication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Monica Feeley (b) (4)	20 Nov 2020 20:07:50
User entered 'PAIN FROM SURGERY FOR SPINAL STENOSIS' reason for change: Data Entry Error	Monica Feeley (b) (4)	20 Nov 2020 20:07:50
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:23:24
User entered 'Pain from spine surgery'	Alexander Mills (b) (4)	10 Nov 2020 22:12:14

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
Query 'dose for hydrocodone is 7.5mg, together it is 7.5-325mg, please review and edit' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	20 Nov 2020 20:09:01
User entered '7.5-325' reason for change: Data Entry Error	Monica Feeley (b) (4)	20 Nov 2020 20:08:57
User opened query 'dose for hydrocodone is 7.5mg, together it is 7.5-325mg, please review and edit' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 16:25:13
User entered '325'	Alexander Mills (b) (4)	10 Nov 2020 22:12:14

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:25:17
User entered 'mg (mg)'	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 22:12:14

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:27:55

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:25:20
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:12:14
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
Query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please review if the alternative is appropriate and consider updating the frequency to the available equivalent rather than Other. Thank you.' answered with 'every 6 hours' (Site from DM).	Monica Feeley (b) (4)	20 Nov 2020 20:07:22
User opened query 'Per CDM: Four times daily is an available option in the drop down for frequency. Please review if the alternative is appropriate and consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 14:06:29
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:25:25
User entered 'other (OTHER)'	Alexander Mills (b) (4)	10 Nov 2020 22:12:14

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:25:28
User entered 'Every 6 hours'	Alexander Mills (b) (4)	10 Nov 2020 22:12:14
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:25:31
User entered 'Oral (ORAL)'	Alexander Mills (b) (4)	10 Nov 2020 22:12:14
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:27:55

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:25:35
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:12:14
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
Query 'Per source EMR: start date is 05Oct20' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	20 Nov 2020 20:08:49
User entered '05 Oct 2020' reason for change: Data Entry Error	Monica Feeley (b) (4)	20 Nov 2020 20:08:41
User opened query 'Per source EMR: start date is 05Oct20' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 19:16:05
Query 'per DS start date is 05Oct20, please review and edit' canceled (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 19:15:34
User opened query 'per DS start date is 05Oct20, please review and edit' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 16:26:05
User entered '2 Oct 2020'	Alexander Mills (b) (4)	10 Nov 2020 22:12:14

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:26:54
User entered '0'	Alexander Mills (b) (4)	10 Nov 2020 22:12:14

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Monica Feeley (b) (4)	20 Nov 2020 20:21:15
User entered 'Yes (Y)'	Alexander Mills (b) (4)	10 Nov 2020 22:12:14

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:27:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '14 Oct 2020' reason for change: Data Entry Error	Monica Feeley (b) (4)	20 Nov 2020 20:21:15
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:12:14

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:26:56
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 22:12:14

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:12:14

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:12:14

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 26 Nov 2020 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:12:14

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:27:55

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 12:14:27
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 12:14:27
User closed query 'discharge summary mentions 5% lidocaine patch, please check' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 22:34:05
Query 'discharge summary mentions 5% lidocaine patch, please check' answered with 'medication notes state 4%. Was likely recorded into discharge summary incorrectly.' (Site from CRA).	Monica Feeley (b) (4) (b) (4)	20 Nov 2020 20:10:06
Data point term sent to Coder	System	20 Nov 2020 20:09:17
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:03:51
User opened query 'discharge summary mentions 5% lidocaine patch, please check' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 16:50:59
Data point term sent to Coder	System	10 Nov 2020 22:14:18
User entered 'Lidocaine Patch (4%)'	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 22:13:41

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:27:55

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:04:05
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 22:13:46
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 22:13:46
User entered 'No (N)' reason for change: Data Entry Error	Alexander Mills (b) (4)	10 Nov 2020 22:13:46
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 22:13:41
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:13:41

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:27:55

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:34:09
User closed query 'Please check Indication.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 22:34:08
Query 'Please check Indication.' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	20 Nov 2020 20:09:15
User entered 'PAIN FROM SURGERY FOR SPINAL STENOSIS' reason for change: Data Entry Error	Monica Feeley (b) (4)	20 Nov 2020 20:09:11
User opened query 'Please check Indication.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 16:49:06
User entered 'Pain from spine'	Alexander Mills (b) (4)	10 Nov 2020 22:13:41

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:27:55

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:04:06
User entered '1'	Alexander Mills (b) (4)	10 Nov 2020 22:13:41
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:27:55

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:04:08
User entered 'Other (OTHER)'	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 22:13:41

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:27:55

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:04:10
User entered 'Application'	Alexander Mills (b) (4)	10 Nov 2020 22:13:41
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:27:55

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:04:12
User entered 'as needed (PRN)'	Alexander Mills (b) (4)	10 Nov 2020 22:13:41
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:27:55

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:04:14
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:13:41
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:27:55

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:04:17
User entered 'Topical (TOPICAL)'	Alexander Mills (b) (4)	10 Nov 2020 22:13:41
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:27:55

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:04:19
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:13:41
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:27:55

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:04:26
User entered '4 Oct 2020'	Alexander Mills (b) (4)	10 Nov 2020 22:13:41

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:27:55

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:04:28
User entered '0'	Alexander Mills (b) (4) (b) (4)	10 Nov 2020 22:13:41

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:27:55

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:34:20
DataPoint Un-verified.	Monica Feeley (b) (4)	20 Nov 2020 20:18:31
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	20 Nov 2020 20:18:31
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:04:30
User entered 'Yes (Y)'	Alexander Mills (b) (4)	10 Nov 2020 22:13:41

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:27:55

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Nov 2020 22:34:18
User closed query 'Source EMR: stop date is 06Oct20, please review and edit. Also check discharge summary for 5% patch, add new entry as required.' (Site from CRA).	(b) (4), (b) (6)	20 Nov 2020 22:34:16
User closed query 'Ongoing is Yes, however End dateSystem is provided. Please correct.' (Site from System).		20 Nov 2020 20:18:31
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	20 Nov 2020 20:18:19
User entered '06 Oct 2020' reason for change: Data Entry Error	Monica Feeley (b) (4)	20 Nov 2020 20:18:19
User closed query 'Ongoing is Yes, however End dateSystem is provided. Please correct.' (Site from System).		20 Nov 2020 20:18:07
User entered empty; reason for change Data Entry Error	Monica Feeley (b) (4)	20 Nov 2020 20:18:07
Query 'Source EMR: stop date is 06Oct20, please review and edit. Also check discharge summary for 5% patch, add new entry as required.' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	20 Nov 2020 20:17:57
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	20 Nov 2020 20:10:38
User entered '06 Oct 2020' reason for change: Data Entry Error	Monica Feeley (b) (4)	20 Nov 2020 20:10:38
User opened query 'Source EMR: stop date is 06Oct20, please review and edit. Also check discharge summary for 5% patch, add new entry as required.' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 19:05:16
User entered empty.	Alexander Mills (b) (4)	10 Nov 2020 22:13:41

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:27:55

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:05:45
User entered 'No (N)'	Alexander Mills (b) (4)	10 Nov 2020 22:13:41
	(b) (4)	

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:27:55

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:13:41

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:27:55

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:13:41

US3432208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 26 Nov 2020 09:27:55

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 22:13:41

US3432208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:27:55

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 15:00:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Oct 2020 14:08:40

US3432208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:27:55

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:55:52
User entered '02 Oct 2020'	(b) (4), (b) (6)	13 Oct 2020 14:19:49

US3432208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:27:55

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 20:27:54
User closed query 'Source concomitant procedures log mentions: Discectomy anterior cervical spine fusion.: please check and and edit' (Site from CRA).	(b) (4), (b) (6)	02 Nov 2020 20:27:53
Query 'Source concomitant procedures log mentions: Discectomy anterior cervical spine fusion.: please check and and edit' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	30 Oct 2020 14:28:38
User entered 'Discectomy anterior cervical spine fusion' reason for change: Per Query Resolution	(b) (4)	30 Oct 2020 14:28:30
DataPoint Un-verified.	(b) (4), (b) (6)	23 Oct 2020 14:55:59
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:55:52
User opened query 'Source concomitant procedures log mentions: Discectomy anterior cervical spine fusion.: please check and and edit' (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 14:26:46
User entered 'Spinal Stenosis'	(b) (4), (b) (6)	13 Oct 2020 14:19:49

US3432208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:27:55

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:55:52
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	13 Oct 2020 14:19:49

US3432208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 26 Nov 2020 09:27:55

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:55:52
User entered empty.	(b) (4), (b) (6)	13 Oct 2020 14:19:49

US3432208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:27:55

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:48:39
User entered '07 Sep 2020'	Monica Feeley (b) (4) (b) (4)	30 Oct 2020 14:29:38

US3432208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:27:55

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:48:42
User entered 'Cervical Spine MRI'	Monica Feeley (b) (4) (b) (4)	30 Oct 2020 14:29:38

US3432208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:27:55

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:48:43
User entered 'Adverse Event (AE)'	Monica Feeley (b) (4) (b) (4)	30 Oct 2020 14:29:38

US3432208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 26 Nov 2020 09:27:55

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 16:48:45
User entered empty.	Monica Feeley (b) (4) (b) (4)	30 Oct 2020 14:29:38

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:47
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'USA-US078-2020-MRNA-1273-P301000004'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:48
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'Yes (Y)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'Yes (Y)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'Lindsey'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'Baden'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'MA'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 15:08:10
User entered 'US'	System	14 Oct 2020 12:02:08

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Nov 2020 00:19:08
User entered '4'	System	11 Nov 2020 17:58:55
User entered '3'	System	02 Nov 2020 13:46:37
User entered '2'	System	16 Oct 2020 15:08:22
User entered '1'	System	14 Oct 2020 12:02:08

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:47
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'USA-US078-2020-MRNA-1273-P301000004'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:48
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'Yes (Y)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'Yes (Y)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'Lindsey'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'Baden'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'MA'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 15:08:10
User entered 'US'	System	14 Oct 2020 12:02:08

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Nov 2020 00:19:08
User entered '4'	System	11 Nov 2020 17:58:55
User entered '3'	System	02 Nov 2020 13:46:37
User entered '2'	System	16 Oct 2020 15:08:22
User entered '1'	System	14 Oct 2020 12:02:08

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:27:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
User entered '14/Oct/2020 08:02'	System	14 Oct 2020 12:02:08

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 26 Nov 2020 09:27:55

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 15:08:10
User entered '1'	(b) (4), (b) (6)	14 Oct 2020 12:02:08

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:47
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'USA-US078-2020-MRNA-1273-P301000004'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:48
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'Yes (Y)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'Yes (Y)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'Lindsey'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'Baden'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'MA'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 15:08:10
User entered 'US'	System	14 Oct 2020 12:02:08

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Nov 2020 00:19:08
User entered '4'	System	11 Nov 2020 17:58:55
User entered '3'	System	02 Nov 2020 13:46:37
User entered '2'	System	16 Oct 2020 15:08:22
User entered '1'	System	14 Oct 2020 12:02:08

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:27:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
User entered '16/Oct/2020 11:08'	System	16 Oct 2020 15:08:22

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 26 Nov 2020 09:27:55

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)
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 20:51:23
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
User entered '1'	(b) (4), (b) (6)	16 Oct 2020 15:08:22

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:47
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'USA-US078-2020-MRNA-1273-P301000004'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:48
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'Yes (Y)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'Yes (Y)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'Lindsey'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'Baden'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'MA'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 15:08:10
User entered 'US'	System	14 Oct 2020 12:02:08

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Nov 2020 00:19:08
User entered '4'	System	11 Nov 2020 17:58:55
User entered '3'	System	02 Nov 2020 13:46:37
User entered '2'	System	16 Oct 2020 15:08:22
User entered '1'	System	14 Oct 2020 12:02:08

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 26 Nov 2020 09:27:55

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)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 17:58:43
User entered '0'	(b) (4), (b) (6)	02 Nov 2020 13:46:37

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:47
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'USA-US078-2020-MRNA-1273-P301000004'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:48
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'Yes (Y)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'Yes (Y)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'Lindsey'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'Baden'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'MA'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 15:08:10
User entered 'US'	System	14 Oct 2020 12:02:08

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Nov 2020 00:19:08
User entered '4'	System	11 Nov 2020 17:58:55
User entered '3'	System	02 Nov 2020 13:46:37
User entered '2'	System	16 Oct 2020 15:08:22
User entered '1'	System	14 Oct 2020 12:02:08

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:27:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '02/Nov/2020 13:46'	System	02 Nov 2020 13:46:37

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 26 Nov 2020 09:27:55

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)
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 17:58:43
User entered '1'	(b) (4), (b) (6)	02 Nov 2020 13:46:37

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:47
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'USA-US078-2020-MRNA-1273-P301000004'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:48
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'Yes (Y)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'Yes (Y)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'Lindsey'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'Baden'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'MA'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 15:08:10
User entered 'US'	System	14 Oct 2020 12:02:08

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Nov 2020 00:19:08
User entered '4'	System	11 Nov 2020 17:58:55
User entered '3'	System	02 Nov 2020 13:46:37
User entered '2'	System	16 Oct 2020 15:08:22
User entered '1'	System	14 Oct 2020 12:02:08

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:27:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '11/Nov/2020 17:58'	System	11 Nov 2020 17:58:55

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 26 Nov 2020 09:27:55

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)
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 00:18:53
User entered '1'	(b) (4), (b) (6)	11 Nov 2020 17:58:55

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:47
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'USA-US078-2020-MRNA-1273-P301000004'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:48
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'Yes (Y)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'Yes (Y)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'No (N)'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'Lindsey'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'Baden'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 12:02:04
User entered 'MA'	System	14 Oct 2020 12:01:46

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 14:58:51
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 15:08:10
User entered 'US'	System	14 Oct 2020 12:02:08

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 26 Nov 2020 09:27:55

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	24 Nov 2020 00:19:08
User entered '4'	System	11 Nov 2020 17:58:55
User entered '3'	System	02 Nov 2020 13:46:37
User entered '2'	System	16 Oct 2020 15:08:22
User entered '1'	System	14 Oct 2020 12:02:08

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 09:27:55

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User entered '24/Nov/2020 00:19'	System	24 Nov 2020 00:19:08

US3432208

Folder: SAE USA-US078-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 26 Nov 2020 09:27:55

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)	24 Nov 2020 00:19:08