

US3432094 (Prod: Brigham and Womens Hospital)

Generated By: (b) (6)

Generated On: 26 Nov 2020 09:26:20

All time stamps listed in this document are displayed in GMT

US3432094

Form: Participant Creation

Generated On: 26 Nov 2020 09:26:20

[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 09:26:20

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	11 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 09:26:20

Date of Birth (MMM yyyy)	(b) (6) 1944
Age	76
Age Units	YEARS
Age (Derived)	76
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 09:26:20

Date of Informed Consent (<i>dd MMM yyyy</i>)	11 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 09:26:20

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:26:20

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:20

Condition	HISTORY OF LEUKEMIA
Start date (dd MMM yyyy)	UN NOV 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2012
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2011
Start Year (derived)	2011
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:20

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	UN SEP 2007
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)	SEP 2007
Start Year (derived)	2007
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:20

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

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Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:20

Condition	CORONARY STENT
Start date (dd MMM yyyy)	UN SEP 2007
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)	SEP 2007
Start Year (derived)	2007
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:20

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

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:26:20

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

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:26:20

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

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:26:20

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

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:26:20

Condition	PROSTATE CANCER
Start date (dd MMM yyyy)	UN UNK 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2003
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	JAN 2003
Stop Year (derived)	2003

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:26:20

Condition	MENINGIOMA
Start date (dd MMM yyyy)	UN NOV 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2012
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2011
Start Year (derived)	2011
Stop Month and Year (derived)	JAN 2012
Stop Year (derived)	2012

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Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:26:20

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Start Year (derived)	2003
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:20

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	11 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:10 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 14:10
Height (<i>xxx.x</i>)	174 cm
Weight (<i>xxx.x</i>)	90.6 kg
BMI (<i>xxx.x</i>)	29.92469 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 09:26:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 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 09:26:20

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

RETIRED PHYSICIAN

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) True

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

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:26:20

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	11 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 09:26:20

What was the date of randomization? (dd MMM yyyy) 11 AUG 2020

What was the participant's randomization number? 185402

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 09:26:20

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 09:26:20

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)	11 AUG 2020
Time of assessment (00:00-23:59)	14:10 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 14:10
Temperature (xxx.x)	37.1 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	135 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:20

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)	11 AUG 2020
Time of assessment (00:00-23:59)	15:53 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 15:53
Temperature (xxx.x)	36.9 C
Route of measurement	Oral ☒ Axillary ☐ Other ☐
If Other, specify	
Pulse (xxx)	46 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:20

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 09:26:20

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)	11 AUG 2020
What was the treatment time? (00:00-23:59)	15:22 (24 HR)
Treatment Date and Time (derived)	11 AUG 2020 15:22
Which arm was used to give treatment?	Left Arm ☐
	Right Arm ☒
What was the frequency of the study treatment dosing?	ONCE
What was the route of administration for the study treatment?	INTRAMUSCULAR

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:20

Was the sample collected?

Yes ☒

No ☐

Collection date (*dd MMM yyyy*)

11 AUG 2020

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

14:20 (24 HR)

Collection date and time (derived)

11 AUG 2020 14:20

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:26:20

Collection date (<i>dd MMM yyyy</i>)			11 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	14:25	11 AUG 2020 14:25
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:26:20

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 09:26:20

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 16:00

PC Open Date & Time

11 AUG 2020 15:42

PC Close Date & Time

11 AUG 2020 18:12

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.3 °F

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

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

PC Time Stamp	11 AUG 2020 23:21
PC Open Date & Time	11 AUG 2020 19:07
PC Close Date & Time	12 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 23:13

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:20

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

95.9 °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

13 AUG 2020 23:16

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.5 °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

14 AUG 2020 18:31

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.2 °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

15 AUG 2020 23:16

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 22:58

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:20

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 23:38

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

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

11 AUG 2020 16:01

PC Open Date & Time

11 AUG 2020 15:42

PC Close Date & Time

11 AUG 2020 18:12

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

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

11 AUG 2020 23:22

PC Open Date & Time

11 AUG 2020 19:07

PC Close Date & Time

12 AUG 2020 11:59

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:20

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 - **SWELLING/HARDNESS AT INJECTION SITE**
(in mm)

50

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 23:14

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:20

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 - **SWELLING/HARDNESS AT INJECTION SITE**
(in mm)

20

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 23:17

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:20

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 - **SWELLING/HARDNESS AT INJECTION SITE**
(in mm)

15

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 18:32

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:20

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 - **SWELLING/HARDNESS AT INJECTION SITE**
(in mm)

10

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 23:17

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:20

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

16 AUG 2020 22:59

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:20

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

17 AUG 2020 23:38

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 16:01
PC Open Date & Time	11 AUG 2020 15:42
PC Close Date & Time	11 AUG 2020 18:12

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 23:23
PC Open Date & Time	11 AUG 2020 19:07
PC Close Date & Time	12 AUG 2020 11:59

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:20

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 ☒

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:20

Yes ☐	
PC Time stamp	12 AUG 2020 23:15
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:20

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 ☒

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:20

Yes ☐	
PC Time stamp	13 AUG 2020 23:17
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:20

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 ☒

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:20

Yes ☐	
PC Time stamp	14 AUG 2020 18:32
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:20

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 ☒

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:20

Yes ☐	
PC Time stamp	15 AUG 2020 23:17
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:20

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 ☒

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:20

Yes ☐	
PC Time stamp	16 AUG 2020 22:59
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:20

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 ☒

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:20

Yes ☐	
PC Time stamp	17 AUG 2020 23:39
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

DAY 8

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 ☐

PC Time Stamp 18 AUG 2020 23:19

PC Open Date & Time 18 AUG 2020 12:00

PC Close Date & Time 19 AUG 2020 11:59

US3432094

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	18 AUG 2020 23:19
PC Open Date & Time	18 AUG 2020 12:00
PC Close Date & Time	19 AUG 2020 11:59

US3432094

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:20

Was Contact Attempted?

Yes ☒

No ☐

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

18 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432094

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432094

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432094

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432094

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432094

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432094

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:26:20

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	10 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT2

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:20

Timepoint	Pre-Dose ☒
	Post-Dose ☐
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	9:06 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 9:06
Temperature (xxx.x)	98.1 F
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)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:20

Timepoint	Pre-Dose ☐
	Post-Dose ☒
Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	10:35 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 10:35
Temperature (xxx.x)	97.9 F
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (xxx)	48 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	146 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3432094

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

US3432094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:26:20

Was study treatment given?	Yes ☒
	No ☐
If No, reason not given	Participant declined due to Adverse Event ☐
	Physician withheld dose due to Adverse Event ☐
	Death ☐
	Lost To Follow-Up ☐
	Physician Decision ☐
	Pregnancy ☐
	Protocol Deviation ☐
	Study Terminated by Sponsor ☐
	Withdrawal of Consent by Participant ☐
	Confirmed COVID-19 ☐
	Other ☐
If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify	
What was the study treatment?	MRNA-1273 OR PLACEBO
What was the treatment date? (dd MMM yyyy)	10 SEP 2020
What was the treatment time? (00:00-23:59)	10:05 (24 HR)
Treatment Date and Time (derived)	10 SEP 2020 10:05
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

US3432094

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:20

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	10 SEP 2020
Collection time (<i>00:00-23:59</i>)	9:50 (24 HR)
Collection date and time (derived)	10 SEP 2020 9:50

US3432094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:26:20

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

US3432094

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

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

97.9 °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

10 SEP 2020 10:42

PC Open Date & Time

10 SEP 2020 10:25

PC Close Date & Time

10 SEP 2020 12:55

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

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 97.6 °F

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

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

PC Time Stamp	10 SEP 2020 21:44
PC Open Date & Time	10 SEP 2020 13:50
PC Close Date & Time	11 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:20

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

98.3 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

11 SEP 2020 18:37

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:20

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	97.3 °F
Was any MEDICATION TAKEN today for pain or fever ?	Yes ☒
	No ☐

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

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

PC Time Stamp	12 SEP 2020 22:29
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 00:06

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:20

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

97.8 °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

14 SEP 2020 22:10

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:20

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

97.5 °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

15 SEP 2020 21:53

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:20

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

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

17 SEP 2020 00:20

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 10:43

PC Open Date & Time

10 SEP 2020 10:25

PC Close Date & Time

10 SEP 2020 12:55

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

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 - **SWELLING/HARDNESS AT INJECTION SITE**
(in mm)

15

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 21:45

PC Open Date & Time

10 SEP 2020 13:50

PC Close Date & Time

11 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:20

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 - **SWELLING/HARDNESS AT INJECTION SITE**
(in mm)

30

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 18:38

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:20

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 - **SWELLING/HARDNESS AT INJECTION SITE**
(in mm)

40

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 22:30

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:20

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 ☐

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

50

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

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

Yes ☒

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE
(in mm)**

50

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 00:00

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:20

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 ☐

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

50

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

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

Yes ☒

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE
(in mm)**

40

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 22:12

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:20

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 ☐

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

40

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

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

Yes ☒

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE
(in mm)**

40

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 21:55

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:20

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 - **SWELLING/HARDNESS AT INJECTION SITE**
(in mm)

15

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 00:21

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 10:43
PC Open Date & Time	10 SEP 2020 10:25
PC Close Date & Time	10 SEP 2020 12:55

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 21:46
PC Open Date & Time	10 SEP 2020 13:50
PC Close Date & Time	11 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:20

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 ☒

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:20

Yes ☐	
PC Time stamp	11 SEP 2020 18:39
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:20

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 ☒

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:20

Yes ☐	
PC Time stamp	12 SEP 2020 22:31
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:20

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 ☒

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:20

Yes ☐	
PC Time stamp	14 SEP 2020 00:01
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:20

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 ☒

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:20

Yes ☐	
PC Time stamp	14 SEP 2020 22:12
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:20

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 ☒

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:20

Yes ☐	
PC Time stamp	15 SEP 2020 21:56
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:20

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 ☒

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:20

Yes ☐	
PC Time stamp	17 SEP 2020 00:21
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

DAY 8

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 ☐

PC Time Stamp	17 SEP 2020 20:09

PC Open Date & Time	17 SEP 2020 12:00

PC Close Date & Time	18 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(9)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

DAY 9

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 ☐

PC Time Stamp

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(10)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

DAY 10

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 ☐

PC Time Stamp

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

DAY 8

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

Yes ☒

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE**
(in mm)

10

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

PC Time stamp 17 SEP 2020 20:10

PC Open Date & Time 17 SEP 2020 12:00

PC Close Date & Time 18 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Swelling_Day(9)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

DAY 9

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

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE**
(in mm)

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

PC Time stamp

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Swelling_Day(10)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

DAY 10

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

Yes ☐

No ☐

Please record - **SWELLING/HARDNESS AT INJECTION SITE**
(in mm)

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

PC Time stamp

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp

17 SEP 2020 20:10

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☒ Yes ☐
PC Time stamp	17 SEP 2020 20:10
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐
	Yes ☐
PC Time stamp	
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3432094

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No ☐
	Yes ☐
PC Time stamp	
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3432094

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:20

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432094

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432094

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:20

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

US3432094

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432094

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:20

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

US3432094

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432094

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:26:20

Was this visit performed?	Yes ☒
	No ☐
Visit date (dd MMM yyyy)	8 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐
	Clinic ☒
Folder OID	VISIT3

US3432094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:20

Were vital signs assessed?	Yes ☒
	No ☐
Date of assessment (<i>dd MMM yyyy</i>)	8 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	09:54 (24 HR)
Vital Signs Date and Time (derived)	8 OCT 2020 09:54
Temperature (<i>xxx.x</i>)	037.0 C
Route of measurement	Oral ☒
	Axillary ☐
	Other ☐
If Other, specify	
Pulse (<i>xxx</i>)	047 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	014 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	067 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3432094

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:20

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

8 OCT 2020

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

US3432094

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:20

Was the sample collected?	Yes ☒
	No ☐
Collection date (<i>dd MMM yyyy</i>)	8 OCT 2020
Collection time (<i>00:00-23:59</i>)	09:58 (24 HR)
Collection date and time (derived)	8 OCT 2020 09:58

US3432094

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 OCT 2020 12:08:30

Patient Cloud Open Date & Time

11 OCT 2020 00:01

Patient Cloud Close Date & Time

15 OCT 2020 23:59

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

20 OCT 2020 12:04:48

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☒ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☒
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☒
Date and time of submission	29 OCT 2020 12:08:46
Patient Cloud Open Date & Time	25 OCT 2020 00:01
Patient Cloud Close Date & Time	29 OCT 2020 23:59

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 12:36:35

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2020 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2020 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 2020 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2020 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 OCT 2020 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2020 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2020 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	☐
Chills	☐
Cough	☐
Shortness of breath	☐
Difficulty breathing	☐
Fatigue	☐
Muscle aches	☐
Body aches	☐
Headache	☐
New loss of taste	☐
New loss of smell	☐
Sore throat	☐
Congestion	☐
Runny nose	☐
Nausea	☐
Vomiting	☐
Diarrhea	☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2020 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2020 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2020 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2020 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2020 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2020 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2020 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

08 MAR 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

19 APR 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

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24 JAN 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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31 JAN 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

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07 FEB 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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14 FEB 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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21 FEB 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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28 FEB 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

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07 MAR 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

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14 MAR 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

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21 MAR 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

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28 MAR 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

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11 JUL 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

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14 JUL 2022 00:01

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18 JUL 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

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21 JUL 2022 00:01

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25 JUL 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

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28 JUL 2022 00:01

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01 AUG 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

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08 AUG 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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15 AUG 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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22 AUG 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 AUG 2022 00:01

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29 AUG 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

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05 SEP 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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12 SEP 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you 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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15 SEP 2022 00:01

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19 SEP 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

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26 SEP 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

Date and time of submission

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03 OCT 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3432094

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:20

Was Contact Attempted?

Yes ☒

No ☐

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

3 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3432094

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:20

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3432094

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:20

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

US3432094

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:20

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3432094

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 26 Nov 2020 09:26:20

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 ☐

US3432094

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 26 Nov 2020 09:26:20

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3432094

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:26:20

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:20

AEID	
Adverse event	INSECT BITE
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)	7 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)	14 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	
Persistent or significant disability or incapacity	False
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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:20

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☒ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only) _____	

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:20

AEID	
Adverse event	IPILATERAL LYMPHADENOPATHY (RIGHT POSTERIOR CERVICAL CHAIN, RIGHT POSTERIOR MANDIBULAR, RIGHT SUPRACLAVICULAR)
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)	10 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)	08 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☒ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ☒
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes ☐

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:20

	No	☐
	Unknown	☐
Number of Days in ICU		
Persistent or significant disability or incapacity	False	
Congenital anomaly or birth defect	False	
Other medically important event	False	
Relationship to investigational product	Not Related	☐
	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	True	
Concomitant Medication	False	
Concomitant Procedure	False	
Outcome	Fatal	☐
	Not Recovered/Not Resolved	☐
	Recovered/Resolved	☒
	Recovered/Resolved with Sequelae	☐
	Recovering/Resolving	☐
	Unknown	☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:		
Narrative		
Serious Adverse Event Derived (CSA Programming Field Only)	0	
Medically Attended AE Derived (CSA Programming Field Only)	0	
Admitted to ICU Derived (CSA Programming Field Only)		

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:20

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

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:20

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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☒ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3432094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:26:20

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

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:26:20

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	PARTICIPANT WAS ADMITTED TO THE HOSPITAL ON 23NOV2020 FOR A CRANIOPLASTY AND CRANIECTOMY FOR MENINGIOMA WHICH IS A PREEXISTING CONDITION.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:26:20

Admitted to ICU Derived (CSA Programming Field Only)

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:26:20

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

Yes ☒

No ☐

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

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:20

Name of Medication	LEVOTHYROXINE
Prophylaxis	Yes ☐ No ☒
Indication	PRE-EXISTING HYPOTHYROIDISM
Dose per administration	150
Dose unit	mg ☐ ug ☒ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☒ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:20

	Intramuscular	☐
	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN	UNK 1990
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	☒

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:20

Name of Medication	ASPIRIN
Prophylaxis	Yes ☐ No ☒
Indication	CORONARY ARTERY DISEASE
Dose per administration	81
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 ☐

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:20

	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 1990
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	☒

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:20

Name of Medication	IRBESARTAN
Prophylaxis	Yes ☐ No ☒
Indication	HYPERTENSION
Dose per administration	150
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ☐ twice daily ☒ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:20

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 1990
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 ☒

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:20

Name of Medication	ESCITALOPRAM
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 ☐

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:20

	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 2003
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	☒

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:20

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

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:20

	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	☒

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:20

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

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:20

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

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:20

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

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:20

	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 1990
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	☒

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:20

Name of Medication	TYLENOL
Prophylaxis	Yes ☐ No ☒
Indication	SORENESS AT INJECTION SITE
Dose per administration	1000
Dose unit	mg ☒ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify _____	
Frequency	once daily ☐ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☒ once ☐ unknown ☐ other ☐
If frequency is Other, specify _____	
Route of administration	Oral ☒ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐ Intramuscular ☐

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:20

	Respiratory (Inhalation)	☐
	Intralesional	☐
	Intraperitoneal	☐
	Nasal	☐
	Vaginal	☐
	Rectal	☐
	Intravenous	☐
	Intravenous Bolus	☐
	Intravenous Drip	☐
	Other	☐
If route of administration is Other, specify		
Start date (dd MMM yyyy)		10 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	☐
	No	☒
If not Ongoing, End date (dd MMM yyyy)		12 SEP 2020
Was this medication taken for solicited event?	Yes	☒
	No	☐
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)		802 ☐
		803 ☐
		804 ☐

US3432094

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 26 Nov 2020 09:26:20

Were any concomitant procedures performed?

Yes ☐

No ☐

If yes, please complete Concomitant Procedures form.

US3432094

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 26 Nov 2020 09:26:20

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

US3432094

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 26 Nov 2020 09:26:20

Date of study discontinuation/completion (dd MMM yyyy)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by ☐

participant (specify)

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (dd MMM yyyy)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

Audit

US3432094 (Prod: Brigham and Womens Hospital)

US3432094

Form: Participant Creation

Generated On: 26 Nov 2020 09:26:20

[Participant ID](#)

Audit	User	Time (GMT)
User entered 'US3432094'	RWS_ENDPOINT ENDPOINT (b) (4) 	11 Aug 2020 17:49:43

US3432094

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:26:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 19:13:54

US3432094

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '11 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	11 Aug 2020 17:49:44

US3432094

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 19:13:54

US3432094

Folder: Screening

Form: Visit Date

Generated On: 26 Nov 2020 09:26:20

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SCRN'	System	11 Aug 2020 19:13:54

US3432094

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:20

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
User entered (b) (6) 1944'	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	11 Aug 2020 17:49:45

US3432094

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:20

[Age](#)

Audit	User	Time (GMT)
User entered '76'	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 19:14:12

US3432094

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:20

[Age Units](#)

Audit	User	Time (GMT)
User entered 'YEARS'	System	11 Aug 2020 19:14:12

US3432094

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:20

[Age \(Derived\)](#)

Audit	User	Time (GMT)
User entered '76'	System	11 Aug 2020 19:14:28

US3432094

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:20

Sex

Audit	User	Time (GMT)
User entered 'Male (M)'	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 19:14:12

US3432094

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:20

[Ethnicity](#)

Audit	User	Time (GMT)
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 19:14:12

US3432094

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:20

White

Audit	User	Time (GMT)
User entered '1'	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 19:14:12

US3432094

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:20

[Black](#)

Audit	User	Time (GMT)
User entered '0'	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 19:14:12

US3432094

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:20

[Asian](#)

Audit	User	Time (GMT)
User entered '0'	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 19:14:12

US3432094

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:20

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
User entered '0'	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 19:14:12

US3432094

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:20

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
User entered '0'	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 19:14:12

US3432094

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:20

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 19:14:12

US3432094

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:20

If race is Other, specify

Audit	User	Time (GMT)
User entered empty.	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 19:14:12

US3432094

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:20

Unknown

Audit	User	Time (GMT)
User entered '0'	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 19:14:12

US3432094

Folder: Screening

Form: Demographics

Generated On: 26 Nov 2020 09:26:20

[Not reported](#)

Audit	User	Time (GMT)
User entered '0'	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 19:14:12

US3432094

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 19:14:28

US3432094

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'Aug 2020'	System	11 Aug 2020 19:14:28

US3432094

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '2020'	System	11 Aug 2020 19:14:28

US3432094

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:20

[Protocol Version](#)

Audit	User	Time (GMT)
User entered 'Amendment 2 (2)'	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 19:14:28

US3432094

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 19:14:28

US3432094

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered empty.	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 19:14:28

US3432094

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:20

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
User entered empty.	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 19:14:28

US3432094

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:20

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 19:14:28

US3432094

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:20

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	11 Aug 2020 17:49:44

US3432094

Folder: Screening

Form: Enrollment

Generated On: 26 Nov 2020 09:26:20

[Enrollment Trigger](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 19:14:33

US3432094

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 19:14:33

US3432094

Folder: Screening

Form: Medical History Summary

Generated On: 26 Nov 2020 09:26:20

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 19:14:38

US3432094

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:20

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Leukaemias, HLT: Leukaemias NEC, PT: Leukaemia, LLT: Leukemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 12:53:24
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 12:53:24
Data point term sent to Coder	System	11 Aug 2020 20:27:14
User entered 'History of leukemia'	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 20:26:21

US3432094

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'un Nov 2011'	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 20:26:21

US3432094

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 20:26:21

US3432094

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 20:26:21

US3432094

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'un UNK 2012'	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 20:26:21

US3432094

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 20:26:21

US3432094

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'Nov 2011'	System	11 Aug 2020 20:26:21

US3432094

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '2011'	System	11 Aug 2020 20:26:21

US3432094

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	11 Aug 2020 20:26:21

US3432094

Folder: Screening

Form: Medical History (1)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '2012'	System	11 Aug 2020 20:26:21

US3432094

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:20

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Per MM: Please review and consider capturing CORONARY ARTERY DISEASE and CORONARY STENT USER separately. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 08:04:02
Query 'Per MM: Please review and consider capturing CORONARY ARTERY DISEASE and CORONARY STENT USER separately. Update as appropriate.' answered with 'updated' (Site from DM).	Monica Feeley (b) (4)	15 Sep 2020 22:15:10
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\23.0.	Coder Import (b) (4)	15 Sep 2020 22:14:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	15 Sep 2020 22:14:54
Data point term sent to Coder	System	15 Sep 2020 22:13:17
Coding entries removed.	Monica Feeley (b) (4)	15 Sep 2020 22:12:33
User entered 'CORONARY ARTERY DISEASE' reason for change: Per Query Resolution	Monica Feeley (b) (4)	15 Sep 2020 22:12:33
User opened query 'Per MM: Please review and consider capturing CORONARY ARTERY DISEASE and CORONARY STENT USER separately. Update as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 09:04:16
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 04:02:09
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 04:02:09
Data point term sent to Coder	System	11 Aug 2020 20:30:24
User entered 'Coronary artery disease w/ stents'	Bruce Bausk (b) (4)	11 Aug 2020 20:29:46

US3432094

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'un Sep 2007'	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 20:29:46

US3432094

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 20:29:46

US3432094

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 20:29:46

US3432094

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered empty.	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 20:29:46

US3432094

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 20:29:46

US3432094

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'Sep 2007'	System	11 Aug 2020 20:29:46

US3432094

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '2007'	System	11 Aug 2020 20:29:46

US3432094

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 20:29:46

US3432094

Folder: Screening

Form: Medical History (2)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 20:29:46

US3432094

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:20

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLT: Cardiac conduction disorders, PT: Atrioventricular block, LLT: Heart block - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 20:31:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 20:31:16
Data point term sent to Coder	System	11 Aug 2020 20:30:25
User entered 'Heart block'	Bruce Bausk (b) (4)	11 Aug 2020 20:30:05

US3432094

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'un UNK 2018'	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 20:30:05

US3432094

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 20:30:05

US3432094

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	11 Aug 2020 21:41:37
User entered 'Yes (Y)' reason for change: Data Entry Error	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:41:37
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	11 Aug 2020 20:30:05
User entered 'No (N)'	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 20:30:05

US3432094

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered empty.	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 20:30:05

US3432094

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 20:30:05

US3432094

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'Jan 2018'	System	11 Aug 2020 20:30:05

US3432094

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '2018'	System	11 Aug 2020 20:30:05

US3432094

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 20:30:05

US3432094

Folder: Screening

Form: Medical History (3)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 20:30:05

US3432094

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:20

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary arterial stent insertion, LLT: Coronary stent placement - version MedDRA\23.0.	Coder Import (b) (4)	15 Sep 2020 22:15:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	15 Sep 2020 22:15:43
Data point term sent to Coder	System	15 Sep 2020 22:14:18
User entered 'CORONARY STENT'	Monica Feeley (b) (4)	15 Sep 2020 22:13:27
DataPoint activated with code reason code Data required.	Monica Feeley (b) (4)	15 Sep 2020 22:12:46
DataPoint inactivated with code reason code Data not required.	Julia Klopfer (b) (4)	11 Aug 2020 21:44:46

US3432094

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User closed query 'Start date is after date of Informed Consent. Please correct.' (Site from System).		15 Sep 2020 22:13:35
User entered 'UN Sep 2007' reason for change: Data Entry Error	Monica Feeley (b) (4)	15 Sep 2020 22:13:35
User opened query 'Start date is after date of Informed Consent. Please correct.' (Site from System).	(b) (4)	15 Sep 2020 22:13:27
User entered 'UN Sep 2020'	Monica Feeley (b) (4)	15 Sep 2020 22:13:27
DataPoint activated with code reason code Data required.	(b) (4)	
	Monica Feeley (b) (4)	15 Sep 2020 22:12:46
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Julia Klopfer (b) (4)	11 Aug 2020 21:44:46
	(b) (4)	

US3432094

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4)	15 Sep 2020 22:13:27
DataPoint activated with code reason code Data required.	Monica Feeley (b) (4)	15 Sep 2020 22:12:46
DataPoint inactivated with code reason code Data not required.	Julia Klopfer (b) (4)	11 Aug 2020 21:44:46

US3432094

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' answered with 'The stent is still in the body. Thanks.' (Site from DM).	Bruce Bausk (b) (4)	27 Oct 2020 15:27:39
User opened query 'Per DM CLR: Ongoing is marked for a surgical procedure. Please review and confirm to add a stop date as surgical procedures are not expected to remain ongoing. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 04:55:58
User entered 'Yes (Y)'	Monica Feeley (b) (4)	15 Sep 2020 22:13:27
DataPoint activated with code reason code Data required.	Monica Feeley (b) (4)	15 Sep 2020 22:12:46
DataPoint inactivated with code reason code Data not required.	Julia Klopfer (b) (4)	11 Aug 2020 21:44:46

US3432094

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4)	15 Sep 2020 22:13:27
DataPoint activated with code reason code Data required.	Monica Feeley (b) (4)	15 Sep 2020 22:12:46
DataPoint inactivated with code reason code Data not required.	Julia Klopfer (b) (4)	11 Aug 2020 21:44:46

US3432094

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4)	15 Sep 2020 22:13:27
DataPoint activated with code reason code Data required.	Monica Feeley (b) (4)	15 Sep 2020 22:12:46
DataPoint inactivated with code reason code Data not required.	Julia Klopfer (b) (4)	11 Aug 2020 21:44:46

US3432094

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'Sep 2007'	System	15 Sep 2020 22:13:35
User entered 'Sep 2020'	System	15 Sep 2020 22:13:27
DataPoint activated with code reason code Data required.	Monica Feeley (b) (4) (b) (4)	15 Sep 2020 22:12:46
DataPoint inactivated with code reason code Data not required.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:44:46

US3432094

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '2007'	System	15 Sep 2020 22:13:35
User entered '2020'	System	15 Sep 2020 22:13:27
DataPoint activated with code reason code Data required.	Monica Feeley (b) (4) (b) (4)	15 Sep 2020 22:12:46
DataPoint inactivated with code reason code Data not required.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:44:46

US3432094

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 22:13:27
DataPoint activated with code reason code Data required.	Monica Feeley (b) (4)	15 Sep 2020 22:12:46
DataPoint inactivated with code reason code Data not required.	Julia Klopfer (b) (4)	11 Aug 2020 21:44:46

US3432094

Folder: Screening

Form: Medical History (4)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered empty.	System	15 Sep 2020 22:13:27
DataPoint activated with code reason code Data required.	Monica Feeley (b) (4)	15 Sep 2020 22:12:46
DataPoint inactivated with code reason code Data not required.	Julia Klopfer (b) (4)	11 Aug 2020 21:44:46

US3432094

Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:20

[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)	11 Aug 2020 21:43:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 21:43:17
Data point term sent to Coder	System	11 Aug 2020 21:42:30
User entered 'Hypertension'	Julia Klopfer (b) (4)	11 Aug 2020 21:42:02
	(b) (4)	

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'UN UNK 1990'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:42:02

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:42:02

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:42:02

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:42:02

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:42:02

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	11 Aug 2020 21:42:02

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '1990'	System	11 Aug 2020 21:42:02

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 21:42:02

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Folder: Screening

Form: Medical History (5)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 21:42:02

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:26:20

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 21:43:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 21:43:18
Data point term sent to Coder	System	11 Aug 2020 21:42:30
User entered 'Hypothyroidism'	Julia Klopfer (b) (4)	11 Aug 2020 21:42:27
	(b) (4)	

US3432094

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'UN UNK 1990'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:42:27

US3432094

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:26:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:42:27

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:26:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:42:27

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:42:27

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:26:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:42:27

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	11 Aug 2020 21:42:27

US3432094

Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '1990'	System	11 Aug 2020 21:42:27

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 21:42:27

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Folder: Screening

Form: Medical History (6)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 21:42:27

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:26:20

[Condition](#)

Audit	User	Time (GMT)
User closed query 'Please confirm if subject is taking any medications for low vit D.' (Site from CRA).	(b) (4), (b) (6)	26 Aug 2020 22:48:18
Query 'Please confirm if subject is taking any medications for low vit D.' answered with 'per clinician, not taking medications' (Site from CRA).	Monica Feeley (b) (4)	18 Aug 2020 15:01:02
User opened query 'Please confirm if subject is taking any medications for low vit D.' (Site from CRA).	(b) (4), (b) (6)	15 Aug 2020 23:04:23
User coded data point as SOC: Investigations, HLGT: Metabolic, nutritional and blood gas investigations, HLT: Vitamin analyses, PT: Vitamin D decreased, LLT: Vitamin D low - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 21:44:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 21:44:18
Data point term sent to Coder	System	11 Aug 2020 21:43:31
User entered 'Low vitamin D'	Julia Klopfer (b) (4)	11 Aug 2020 21:42:47

US3432094

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'UN UNK 1990'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:42:47

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:26:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:42:47

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:26:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:42:47

US3432094

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:42:47

US3432094

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:26:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:42:47

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	11 Aug 2020 21:42:47

US3432094

Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '1990'	System	11 Aug 2020 21:42:47

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 21:42:47

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Folder: Screening

Form: Medical History (7)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 21:42:47

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:26:20

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: Esophageal reflux - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 21:44:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 21:44:18
Data point term sent to Coder	System	11 Aug 2020 21:43:32
User entered 'Esophageal reflux'	Julia Klopfer (b) (4)	11 Aug 2020 21:43:05
	(b) (4)	

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'UN UNK 1990'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:43:05

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:26:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:43:05

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:26:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:43:05

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:43:05

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:26:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:43:05

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Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'Jan 1990'	System	11 Aug 2020 21:43:05

US3432094

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '1990'	System	11 Aug 2020 21:43:05

US3432094

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 21:43:05

US3432094

Folder: Screening

Form: Medical History (8)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 21:43:05

US3432094

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:26:20

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLG: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 21:45:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 21:45:19
Data point term sent to Coder	System	11 Aug 2020 21:44:33
User entered 'Prostate cancer'	Julia Klopfer (b) (4)	11 Aug 2020 21:43:34
	(b) (4)	

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'UN UNK 2003'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:43:34

US3432094

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:26:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:43:34

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:26:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:43:34

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'UN UNK 2003'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:43:34

US3432094

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:26:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:43:34

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'Jan 2003'	System	11 Aug 2020 21:43:34

US3432094

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '2003'	System	11 Aug 2020 21:43:34

US3432094

Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'Jan 2003'	System	11 Aug 2020 21:43:34

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Folder: Screening

Form: Medical History (9)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '2003'	System	11 Aug 2020 21:43:34

US3432094

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:26:20

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Nervous system neoplasms malignant and unspecified NEC, HLT: Nervous system neoplasms unspecified malignancy NEC, PT: Meningioma, LLT: Meningioma - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 21:45:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 21:45:19
Data point term sent to Coder	System	11 Aug 2020 21:44:33
User entered 'Meningioma'	Julia Klopfer (b) (4)	11 Aug 2020 21:44:19
	(b) (4)	

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'UN Nov 2011'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:44:19

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:26:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:44:19

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:26:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:44:19

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Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'UN UNK 2012'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:44:19

US3432094

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:26:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:44:19

US3432094

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'Nov 2011'	System	11 Aug 2020 21:44:19

US3432094

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '2011'	System	11 Aug 2020 21:44:19

US3432094

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'Jan 2012'	System	11 Aug 2020 21:44:19

US3432094

Folder: Screening

Form: Medical History (10)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '2012'	System	11 Aug 2020 21:44:19

US3432094

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:26:20

[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)	18 Aug 2020 15:00:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 15:00:24
Data point term sent to Coder	System	18 Aug 2020 14:59:31
User entered 'Depression'	Monica Feeley (b) (4)	18 Aug 2020 14:58:41
	(b) (4)	

US3432094

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'UN UNK 2003'	Monica Feeley (b) (4) (b) (4)	18 Aug 2020 14:58:41

US3432094

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:26:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	18 Aug 2020 14:58:41

US3432094

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:26:20

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	18 Aug 2020 14:58:41

US3432094

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	18 Aug 2020 14:58:41

US3432094

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:26:20

[Stop date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	18 Aug 2020 14:58:41

US3432094

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'Jan 2003'	System	18 Aug 2020 14:58:41

US3432094

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '2003'	System	18 Aug 2020 14:58:41

US3432094

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 14:58:41

US3432094

Folder: Screening

Form: Medical History (11)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered empty.	System	18 Aug 2020 14:58:41

US3432094

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:46:33

US3432094

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:46:33

US3432094

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '14:10'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:46:33

US3432094

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '11 Aug 2020 14:10'	System	11 Aug 2020 21:46:33

US3432094

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '174' cm	Julia Klopfer (b) (4)	11 Aug 2020 21:46:33
DataPoint set to visible.	(b) (4) System	11 Aug 2020 19:14:33

US3432094

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '90.6' kg	Julia Klopfer (b) (4)	11 Aug 2020 21:46:33
DataPoint set to visible.	(b) (4) System	11 Aug 2020 19:14:33

US3432094

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:20

BMI (xxx.x)

Audit	User	Time (GMT)
Amendment Manager: User entered '29.92469'	System	16 Sep 2020 23:52:01
User entered '29.9'	System	11 Aug 2020 21:46:33
DataPoint set to visible.	System	11 Aug 2020 19:14:33

US3432094

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:20

[BMI units](#)

Audit	User	Time (GMT)
User entered 'kg/m2'	System	11 Aug 2020 21:46:33
DataPoint set to visible.	System	11 Aug 2020 19:14:33

US3432094

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:20

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 19:30:45
User entered '37.1' C	Julia Klopfer (b) (4)	11 Aug 2020 21:46:33
	(b) (4)	

US3432094

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:20

[Route of measurement](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 11:57:29
Query 'Data is required. Please provide.' answered with 'No data is listed per (b) (6) request.' (Site from System).	(b) (4), (b) (6)	13 Aug 2020 19:30:54
User opened query 'Data is required. Please provide.' (Site from System).	System	13 Aug 2020 19:30:45
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 19:30:45
User entered 'Oral (Oral)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:46:33

US3432094

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:20

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:46:33

US3432094

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 19:30:45
User entered '60'	Julia Klopfer (b) (4)	11 Aug 2020 21:46:33
	(b) (4)	

US3432094

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:20

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Aug 2020 21:46:33

US3432094

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 19:30:45
User entered '16'	Julia Klopfer (b) (4)	11 Aug 2020 21:46:33
	(b) (4)	

US3432094

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Aug 2020 21:46:33

US3432094

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 19:30:45
User entered '135'	Julia Klopfer (b) (4)	11 Aug 2020 21:46:33
	(b) (4)	

US3432094

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 21:46:33

US3432094

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	13 Aug 2020 19:30:45
User entered '66'	Julia Klopfer (b) (4)	11 Aug 2020 21:46:33
	(b) (4)	

US3432094

Folder: Screening

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 21:46:33

US3432094

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:46:42

US3432094

Folder: Screening

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:20

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	11 Sep 2020 22:46:41
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		10 Sep 2020 14:07:50
User entered '11 Aug 2020'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:46:42

US3432094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:47:38

US3432094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:47:38

US3432094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:47:38

US3432094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:47:38

US3432094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:47:38

US3432094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:47:38

US3432094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:47:38

US3432094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:47:38

US3432094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:47:38

US3432094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:47:38

US3432094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:47:38

US3432094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:20

[Other](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:47:38

US3432094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:20

[Specify](#)

Audit	User	Time (GMT)
User entered 'Retired physician'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:47:38

US3432094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:20

No Risk Identified

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:47:38

US3432094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:47:38

US3432094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:20

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 '1'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:47:38

US3432094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:47:38

US3432094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:47:38

US3432094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:47:38

US3432094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:20

[Other](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:47:38

US3432094

Folder: Screening

Form: Risk of Exposure

Generated On: 26 Nov 2020 09:26:20

[Specify](#)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:47:38

US3432094

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:26:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:47:53

US3432094

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:47:53

US3432094

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:47:53

US3432094

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 26 Nov 2020 09:26:20

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT1'	System	11 Aug 2020 21:47:53

US3432094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '11 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) 	11 Aug 2020 18:19:34

US3432094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:26:20

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 03:37:42
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:37:42
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 18:19:34
User entered '185402' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	11 Aug 2020 18:19:34

US3432094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4) 	11 Aug 2020 18:19:34

US3432094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:48:30

US3432094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:48:30

US3432094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:48:30

US3432094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:26:20

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:48:30

US3432094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:26:20

[Liver Disease](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:48:30

US3432094

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:17:46
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:33:34

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:26:20

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:26:20

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:26:20

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:26:20

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:20

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '14:10'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '11 Aug 2020 14:10'	System	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:20

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '37.1' C	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:20

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:20

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '60'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:20

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '16'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '135'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '66'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:26:20

Height

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 26 Nov 2020 09:26:20

Weight

Audit	User	Time (GMT)
User entered missing code ND - Not Done.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:20

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:20

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)	17 Aug 2020 10:54:14
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Per protocol, 30 mins after vaccine' (Site from System).	Julia Klopfer (b) (4)	11 Aug 2020 21:51:27
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).	(b) (4)	11 Aug 2020 21:51:09
User entered '15:53'	Julia Klopfer (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '11 Aug 2020 15:53'	System	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:20

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '36.9' C	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:20

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:20

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '46'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:20

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '15'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '136'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '64'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	11 Aug 2020 21:51:09

US3432094

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:20

Was the physical examination performed?

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:51:33

US3432094

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:20

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:51:33

US3432094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:20

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 19:45:55

US3432094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:20

If No, reason not given

Audit	User	Time (GMT)
User entered empty.	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 19:45:55

US3432094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered empty.	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 19:45:55

US3432094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:20

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	11 Aug 2020 19:45:55

US3432094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:20

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 19:45:55

US3432094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '15:22'	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 19:45:55

US3432094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '11 Aug 2020 15:22'	System	11 Aug 2020 19:45:55

US3432094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'Right Arm (RIGHT ARM)'	Bruce Bausk (b) (4) (b) (4)	11 Aug 2020 19:45:55

US3432094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	11 Aug 2020 19:45:55

US3432094

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	11 Aug 2020 19:45:55

US3432094

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:40:02

US3432094

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:40:02

US3432094

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '14:20'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:40:02

US3432094

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '11 Aug 2020 14:20'	System	11 Aug 2020 22:40:02

US3432094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:26:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '11 Aug 2020'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:40:19

US3432094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:26:20

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:40:19

US3432094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:26:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:40:19

US3432094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:26:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '14:25'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:40:19

US3432094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '11 Aug 2020 14:25'	System	11 Aug 2020 22:40:19

US3432094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:26:20

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:40:19

US3432094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:26:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:40:19

US3432094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:26:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:40:19

US3432094

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered empty.	System	11 Aug 2020 22:40:19

US3432094

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:56:00

US3432094

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 26 Nov 2020 09:26:20

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 21:56:00

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T16:00:03', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'c6bbd1a6-e1dc-4c96-9ef6-7fee289cc805'	System	11 Aug 2020 20:00:33
User entered 'Yes (Y)'	System	11 Aug 2020 20:00:33

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T16:00:17', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'c6bbd1a6-e1dc-4c96-9ef6-7fee289cc805'	System	11 Aug 2020 20:00:33
User entered '98.4'	System	11 Aug 2020 20:00:33

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T16:00:22', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'c6bbd1a6-e1dc-4c96-9ef6-7fee289cc805'	System	11 Aug 2020 20:00:33
User entered 'No (N)'	System	11 Aug 2020 20:00:33

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T16:00:30', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'c6bbd1a6-e1dc-4c96-9ef6-7fee289cc805'	System	11 Aug 2020 20:00:33
User entered '11 Aug 2020 16:00'	System	11 Aug 2020 20:00:33

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 15:42'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 18:12'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T23:21:36', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'abf6a8b3-96c7-4d19-97a3-93350feafd33'	System	12 Aug 2020 03:21:54
User entered 'Yes (Y)'	System	12 Aug 2020 03:21:54

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T23:21:42', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'abf6a8b3-96c7-4d19-97a3-93350feafd33'	System	12 Aug 2020 03:21:54
User entered '96.3'	System	12 Aug 2020 03:21:54

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T23:21:46', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'abf6a8b3-96c7-4d19-97a3-93350feafd33'	System	12 Aug 2020 03:21:54
User entered 'No (N)'	System	12 Aug 2020 03:21:54

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T23:21:52', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'abf6a8b3-96c7-4d19-97a3-93350feafd33'	System	12 Aug 2020 03:21:54
User entered '11 Aug 2020 23:21'	System	12 Aug 2020 03:21:54

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 19:07'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 2'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-12T23:12:39', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '19e8aa87-c133-45ec-9e10-13f20cddec7b'	System	13 Aug 2020 03:13:01
User entered 'Yes (Y)'	System	13 Aug 2020 03:13:01

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:20

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-12T23:12:46', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '19e8aa87-c133-45ec-9e10-13f20cddec7b' User entered '96.3'	System	13 Aug 2020 03:13:01
	System	13 Aug 2020 03:13:01

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-12T23:12:50', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '19e8aa87-c133-45ec-9e10-13f20cddec7b'	System	13 Aug 2020 03:13:01
User entered 'No (N)'	System	13 Aug 2020 03:13:01

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-12T23:13:00', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '19e8aa87-c133-45ec-9e10-13f20cddec7b'	System	13 Aug 2020 03:13:01
User entered '12 Aug 2020 23:13'	System	13 Aug 2020 03:13:01

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 3'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-13T23:16:12', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '678b7bc3-8acc-4d0d-b8a4-7a71d81e3d65'	System	14 Aug 2020 03:16:31
User entered 'Yes (Y)'	System	14 Aug 2020 03:16:31

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-13T23:16:19', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '678b7bc3-8acc-4d0d-b8a4-7a71d81e3d65'	System	14 Aug 2020 03:16:31
User entered '95.9'	System	14 Aug 2020 03:16:31

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-13T23:16:23', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '678b7bc3-8acc-4d0d-b8a4-7a71d81e3d65'	System	14 Aug 2020 03:16:31
User entered 'No (N)'	System	14 Aug 2020 03:16:31

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-13T23:16:28', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '678b7bc3-8acc-4d0d-b8a4-7a71d81e3d65'	System	14 Aug 2020 03:16:31
User entered '13 Aug 2020 23:16'	System	14 Aug 2020 03:16:31

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 4'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-14T18:31:39', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '450f3368-b4b5-43ee-b675-1e1c2f7a524e'	System	14 Aug 2020 22:31:57
User entered 'Yes (Y)'	System	14 Aug 2020 22:31:57

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-14T18:31:46', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '450f3368-b4b5-43ee-b675-1e1c2f7a524e'	System	14 Aug 2020 22:31:57
User entered '96.5'	System	14 Aug 2020 22:31:57

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-14T18:31:49', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '450f3368-b4b5-43ee-b675-1e1c2f7a524e'	System	14 Aug 2020 22:31:57
User entered 'No (N)'	System	14 Aug 2020 22:31:57

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-14T18:31:53', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '450f3368-b4b5-43ee-b675-1e1c2f7a524e'	System	14 Aug 2020 22:31:57
User entered '14 Aug 2020 18:31'	System	14 Aug 2020 22:31:57

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 5'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-15T23:16:27', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'a9c9b5df-49b4-4f9e-b181-aaaad5b88559'	System	16 Aug 2020 03:16:45
User entered 'Yes (Y)'	System	16 Aug 2020 03:16:45

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-15T23:16:34', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'a9c9b5df-49b4-4f9e-b181-aaaad5b88559'	System	16 Aug 2020 03:16:45
User entered '96.2'	System	16 Aug 2020 03:16:45

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-15T23:16:39', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'a9c9b5df-49b4-4f9e-b181-aaaad5b88559'	System	16 Aug 2020 03:16:45
User entered 'No (N)'	System	16 Aug 2020 03:16:45

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-15T23:16:43', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'a9c9b5df-49b4-4f9e-b181-aaaad5b88559'	System	16 Aug 2020 03:16:45
User entered '15 Aug 2020 23:16'	System	16 Aug 2020 03:16:45

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 6'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-16T22:58:27', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'e0bf1b2f-2485-408c-968a-0deb9ee75a4e'	System	17 Aug 2020 02:58:42
User entered 'Yes (Y)'	System	17 Aug 2020 02:58:42

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-16T22:58:33', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'e0bf1b2f-2485-408c-968a-0deb9ee75a4e'	System	17 Aug 2020 02:58:42
User entered '96.3'	System	17 Aug 2020 02:58:42

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-16T22:58:36', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'e0bf1b2f-2485-408c-968a-0deb9ee75a4e'	System	17 Aug 2020 02:58:42
User entered 'No (N)'	System	17 Aug 2020 02:58:42

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-16T22:58:40', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'e0bf1b2f-2485-408c-968a-0deb9ee75a4e'	System	17 Aug 2020 02:58:42
User entered '16 Aug 2020 22:58'	System	17 Aug 2020 02:58:42

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 7'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-17T23:38:13', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '426eb8e4-7888-4906-8aae-6165b2082a73'	System	18 Aug 2020 03:38:32
User entered 'Yes (Y)'	System	18 Aug 2020 03:38:32

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-17T23:38:19', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '426eb8e4-7888-4906-8aae-6165b2082a73'	System	18 Aug 2020 03:38:32
User entered '97.0'	System	18 Aug 2020 03:38:32

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-17T23:38:24', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '426eb8e4-7888-4906-8aae-6165b2082a73'	System	18 Aug 2020 03:38:32
User entered 'No (N)'	System	18 Aug 2020 03:38:32

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-17T23:38:27', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '426eb8e4-7888-4906-8aae-6165b2082a73'	System	18 Aug 2020 03:38:32
User entered '17 Aug 2020 23:38'	System	18 Aug 2020 03:38:32

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T16:00:47', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'af774d9b-ae5a-4045-aa6f-0582a27c9315'	System	11 Aug 2020 20:01:20
User entered 'None (1)'	System	11 Aug 2020 20:01:20

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T16:00:54', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'af774d9b-ae5a-4045-aa6f-0582a27c9315'	System	11 Aug 2020 20:01:20
User entered 'No (N)'	System	11 Aug 2020 20:01:20

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T16:00:58', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'af774d9b-ae5a-4045-aa6f-0582a27c9315'	System	11 Aug 2020 20:01:20
User entered 'No (N)'	System	11 Aug 2020 20:01:20

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T16:01:12', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'af774d9b-ae5a-4045-aa6f-0582a27c9315'	System	11 Aug 2020 20:01:20
User entered 'None (1)'	System	11 Aug 2020 20:01:20

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T16:01:17', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'af774d9b-ae5a-4045-aa6f-0582a27c9315'	System	11 Aug 2020 20:01:20
User entered '11 Aug 2020 16:01'	System	11 Aug 2020 20:01:20

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 15:42'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 18:12'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T23:22:03', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'ee0f333f-bc33-4718-bb79-f22556442fb0'	System	12 Aug 2020 03:22:37
User entered 'Does not interfere with activity (2)'	System	12 Aug 2020 03:22:37

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T23:22:07', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'ee0f333f-bc33-4718-bb79-f22556442fb0'	System	12 Aug 2020 03:22:37
User entered 'No (N)'	System	12 Aug 2020 03:22:37

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T23:22:10', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'ee0f333f-bc33-4718-bb79-f22556442fb0'	System	12 Aug 2020 03:22:37
User entered 'No (N)'	System	12 Aug 2020 03:22:37

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T23:22:25', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'ee0f333f-bc33-4718-bb79-f22556442fb0'	System	12 Aug 2020 03:22:37
User entered 'None (1)'	System	12 Aug 2020 03:22:37

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T23:22:34', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'ee0f333f-bc33-4718-bb79-f22556442fb0'	System	12 Aug 2020 03:22:37
User entered '11 Aug 2020 23:22'	System	12 Aug 2020 03:22:37

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 19:07'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 2'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-12T23:13:20', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7fcc7091-70fb-4f1e-8a5e-cc7bd7b3c511'	System	13 Aug 2020 03:14:26
User entered 'Does not interfere with activity (2)'	System	13 Aug 2020 03:14:26

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-12T23:13:25', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7fcc7091-70fb-4f1e-8a5e-cc7bd7b3c511'	System	13 Aug 2020 03:14:26
User entered 'No (N)'	System	13 Aug 2020 03:14:26

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-12T23:13:29', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7fcc7091-70fb-4f1e-8a5e-cc7bd7b3c511'	System	13 Aug 2020 03:14:26
User entered 'Yes (Y)'	System	13 Aug 2020 03:14:26

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:20

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-12T23:13:53', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7fcc7091-70fb-4f1e-8a5e-cc7bd7b3c511'	System	13 Aug 2020 03:14:26
User entered '50'	System	13 Aug 2020 03:14:26

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-12T23:14:13', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7fcc7091-70fb-4f1e-8a5e-cc7bd7b3c511'	System	13 Aug 2020 03:14:26
User entered 'None (1)'	System	13 Aug 2020 03:14:26

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-12T23:14:23', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7fcc7091-70fb-4f1e-8a5e-cc7bd7b3c511'	System	13 Aug 2020 03:14:26
User entered '12 Aug 2020 23:14'	System	13 Aug 2020 03:14:26

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 3'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-13T23:16:35', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '8fe471e5-77c6-426a-99a4-bda727933a66'	System	14 Aug 2020 03:17:19
User entered 'Does not interfere with activity (2)'	System	14 Aug 2020 03:17:19

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-13T23:16:38', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '8fe471e5-77c6-426a-99a4-bda727933a66'	System	14 Aug 2020 03:17:19
User entered 'No (N)'	System	14 Aug 2020 03:17:19

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-13T23:16:42', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '8fe471e5-77c6-426a-99a4-bda727933a66'	System	14 Aug 2020 03:17:19
User entered 'Yes (Y)'	System	14 Aug 2020 03:17:19

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:20

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-13T23:16:53', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '8fe471e5-77c6-426a-99a4-bda727933a66' User entered '20'	System	14 Aug 2020 03:17:19
	System	14 Aug 2020 03:17:19

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-13T23:17:08', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '8fe471e5-77c6-426a-99a4-bda727933a66'	System	14 Aug 2020 03:17:19
User entered 'None (1)'	System	14 Aug 2020 03:17:19

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-13T23:17:16', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '8fe471e5-77c6-426a-99a4-bda727933a66'	System	14 Aug 2020 03:17:19
User entered '13 Aug 2020 23:17'	System	14 Aug 2020 03:17:19

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 4'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-14T18:32:02', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '43016ac0-77f0-48ef-99a1-59a399d0d87b'	System	14 Aug 2020 22:32:41
User entered 'Does not interfere with activity (2)'	System	14 Aug 2020 22:32:41

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-14T18:32:05', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '43016ac0-77f0-48ef-99a1-59a399d0d87b'	System	14 Aug 2020 22:32:41
User entered 'No (N)'	System	14 Aug 2020 22:32:41

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-14T18:32:09', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '43016ac0-77f0-48ef-99a1-59a399d0d87b'	System	14 Aug 2020 22:32:41
User entered 'Yes (Y)'	System	14 Aug 2020 22:32:41

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:20

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-14T18:32:16', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '43016ac0-77f0-48ef-99a1-59a399d0d87b' User entered '15'	System	14 Aug 2020 22:32:41
	System	14 Aug 2020 22:32:41

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-14T18:32:31', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '43016ac0-77f0-48ef-99a1-59a399d0d87b'	System	14 Aug 2020 22:32:41
User entered 'None (1)'	System	14 Aug 2020 22:32:41

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-14T18:32:35', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '43016ac0-77f0-48ef-99a1-59a399d0d87b'	System	14 Aug 2020 22:32:41
User entered '14 Aug 2020 18:32'	System	14 Aug 2020 22:32:41

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 5'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-15T23:16:50', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '4033fb4f-85d7-4ea6-b42b-44f299435952'	System	16 Aug 2020 03:17:11
User entered 'Does not interfere with activity (2)'	System	16 Aug 2020 03:17:11

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-15T23:16:53', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '4033fb4f-85d7-4ea6-b42b-44f299435952'	System	16 Aug 2020 03:17:11
User entered 'No (N)'	System	16 Aug 2020 03:17:11

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-15T23:16:57', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '4033fb4f-85d7-4ea6-b42b-44f299435952'	System	16 Aug 2020 03:17:11
User entered 'Yes (Y)'	System	16 Aug 2020 03:17:11

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:20

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-15T23:17:02', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '4033fb4f-85d7-4ea6-b42b-44f299435952' User entered '10'	System	16 Aug 2020 03:17:11
	System	16 Aug 2020 03:17:11

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-15T23:17:05', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '4033fb4f-85d7-4ea6-b42b-44f299435952'	System	16 Aug 2020 03:17:11
User entered 'None (1)'	System	16 Aug 2020 03:17:11

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-15T23:17:08', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '4033fb4f-85d7-4ea6-b42b-44f299435952'	System	16 Aug 2020 03:17:11
User entered '15 Aug 2020 23:17'	System	16 Aug 2020 03:17:11

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 6'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-16T22:58:50', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'fdc2526b-1c90-4315-bca4-8ab1ff0452a5'	System	17 Aug 2020 02:59:06
User entered 'Does not interfere with activity (2)'	System	17 Aug 2020 02:59:06

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-16T22:58:53', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'fdc2526b-1c90-4315-bca4-8ab1ff0452a5'	System	17 Aug 2020 02:59:06
User entered 'No (N)'	System	17 Aug 2020 02:59:06

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-16T22:58:56', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'fdc2526b-1c90-4315-bca4-8ab1ff0452a5'	System	17 Aug 2020 02:59:06
User entered 'No (N)'	System	17 Aug 2020 02:59:06

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-16T22:59:01', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'fdc2526b-1c90-4315-bca4-8ab1ff0452a5'	System	17 Aug 2020 02:59:06
User entered 'None (1)'	System	17 Aug 2020 02:59:06

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-16T22:59:04', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'fdc2526b-1c90-4315-bca4-8ab1ff0452a5'	System	17 Aug 2020 02:59:06
User entered '16 Aug 2020 22:59'	System	17 Aug 2020 02:59:06

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 7'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-17T23:38:36', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'af61104b-41ce-4ff3-b40a-1d3db0413014'	System	18 Aug 2020 03:38:51
User entered 'Does not interfere with activity (2)'	System	18 Aug 2020 03:38:51

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-17T23:38:40', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'af61104b-41ce-4ff3-b40a-1d3db0413014'	System	18 Aug 2020 03:38:51
User entered 'No (N)'	System	18 Aug 2020 03:38:51

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-17T23:38:42', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'af61104b-41ce-4ff3-b40a-1d3db0413014'	System	18 Aug 2020 03:38:51
User entered 'No (N)'	System	18 Aug 2020 03:38:51

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-17T23:38:46', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'af61104b-41ce-4ff3-b40a-1d3db0413014'	System	18 Aug 2020 03:38:51
User entered 'None (1)'	System	18 Aug 2020 03:38:51

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-17T23:38:49', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'af61104b-41ce-4ff3-b40a-1d3db0413014'	System	18 Aug 2020 03:38:51
User entered '17 Aug 2020 23:38'	System	18 Aug 2020 03:38:51

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T16:01:30', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '23b6d0d3-48be-47b0-b83c-417bf6b9cfb1'	System	11 Aug 2020 20:01:59
User entered 'None (0)'	System	11 Aug 2020 20:01:59

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T16:01:34', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '23b6d0d3-48be-47b0-b83c-417bf6b9cfb1'	System	11 Aug 2020 20:01:59
User entered 'None (0)'	System	11 Aug 2020 20:01:59

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T16:01:38', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '23b6d0d3-48be-47b0-b83c-417bf6b9cfb1'	System	11 Aug 2020 20:01:59
User entered 'None (0)'	System	11 Aug 2020 20:01:59

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T16:01:41', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '23b6d0d3-48be-47b0-b83c-417bf6b9cfb1' User entered 'None (0)'	System	11 Aug 2020 20:01:59
	System	11 Aug 2020 20:01:59

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T16:01:44', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '23b6d0d3-48be-47b0-b83c-417bf6b9cfb1'	System	11 Aug 2020 20:01:59
User entered 'None (0)'	System	11 Aug 2020 20:01:59

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T16:01:46', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '23b6d0d3-48be-47b0-b83c-417bf6b9cfb1'	System	11 Aug 2020 20:01:59
User entered 'None (0)'	System	11 Aug 2020 20:01:59

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T16:01:50', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '23b6d0d3-48be-47b0-b83c-417bf6b9cfb1'	System	11 Aug 2020 20:01:59
User entered 'No (N)'	System	11 Aug 2020 20:01:59

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T16:01:54', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '23b6d0d3-48be-47b0-b83c-417bf6b9cfb1'	System	11 Aug 2020 20:01:59
User entered '11 Aug 2020 16:01'	System	11 Aug 2020 20:01:59

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 15:42'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 18:12'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T23:22:40', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '19445472-b369-4b79-a4b4-ad0241b9fb52'	System	12 Aug 2020 03:23:28
User entered 'None (0)'	System	12 Aug 2020 03:23:28

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T23:23:19', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '19445472-b369-4b79-a4b4-ad0241b9fb52'	System	12 Aug 2020 03:23:28
User entered 'No interference with activity (1)'	System	12 Aug 2020 03:23:28

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T23:22:53', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '19445472-b369-4b79-a4b4-ad0241b9fb52'	System	12 Aug 2020 03:23:28
User entered 'None (0)'	System	12 Aug 2020 03:23:28

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T23:22:56', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '19445472-b369-4b79-a4b4-ad0241b9fb52'	System	12 Aug 2020 03:23:28
User entered 'None (0)'	System	12 Aug 2020 03:23:28

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T23:22:59', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '19445472-b369-4b79-a4b4-ad0241b9fb52'	System	12 Aug 2020 03:23:28
User entered 'None (0)'	System	12 Aug 2020 03:23:28

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T23:23:02', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '19445472-b369-4b79-a4b4-ad0241b9fb52'	System	12 Aug 2020 03:23:28
User entered 'None (0)'	System	12 Aug 2020 03:23:28

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T23:23:07', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '19445472-b369-4b79-a4b4-ad0241b9fb52'	System	12 Aug 2020 03:23:28
User entered 'No (N)'	System	12 Aug 2020 03:23:28

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-11T23:23:27', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '19445472-b369-4b79-a4b4-ad0241b9fb52'	System	12 Aug 2020 03:23:28
User entered '11 Aug 2020 23:23'	System	12 Aug 2020 03:23:28

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Aug 2020 19:07'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 2'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-12T23:14:32', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '05d5f93e-3482-4e28-9cf5-a7e63ca2bed2'	System	13 Aug 2020 03:15:16
User entered 'None (0)'	System	13 Aug 2020 03:15:16

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-12T23:14:39', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '05d5f93e-3482-4e28-9cf5-a7e63ca2bed2'	System	13 Aug 2020 03:15:16
User entered 'No interference with activity (1)'	System	13 Aug 2020 03:15:16

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-12T23:14:43', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '05d5f93e-3482-4e28-9cf5-a7e63ca2bed2'	System	13 Aug 2020 03:15:16
User entered 'None (0)'	System	13 Aug 2020 03:15:16

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-12T23:14:47', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '05d5f93e-3482-4e28-9cf5-a7e63ca2bed2'	System	13 Aug 2020 03:15:16
User entered 'None (0)'	System	13 Aug 2020 03:15:16

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-12T23:14:50', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '05d5f93e-3482-4e28-9cf5-a7e63ca2bed2'	System	13 Aug 2020 03:15:16
User entered 'None (0)'	System	13 Aug 2020 03:15:16

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-12T23:14:53', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '05d5f93e-3482-4e28-9cf5-a7e63ca2bed2'	System	13 Aug 2020 03:15:16
User entered 'None (0)'	System	13 Aug 2020 03:15:16

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-12T23:14:57', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '05d5f93e-3482-4e28-9cf5-a7e63ca2bed2'	System	13 Aug 2020 03:15:16
User entered 'No (N)'	System	13 Aug 2020 03:15:16

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-12T23:15:10', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '05d5f93e-3482-4e28-9cf5-a7e63ca2bed2'	System	13 Aug 2020 03:15:16
User entered '12 Aug 2020 23:15'	System	13 Aug 2020 03:15:16

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:20

[TIMEPOINT](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 3'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-13T23:17:22', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '44618428-044e-42cf-97d6-803c4060cdd7'	System	14 Aug 2020 03:17:59
User entered 'None (0)'	System	14 Aug 2020 03:17:59

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-13T23:17:25', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '44618428-044e-42cf-97d6-803c4060cdd7'	System	14 Aug 2020 03:17:59
User entered 'None (0)'	System	14 Aug 2020 03:17:59

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-13T23:17:28', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '44618428-044e-42cf-97d6-803c4060cdd7'	System	14 Aug 2020 03:17:59
User entered 'None (0)'	System	14 Aug 2020 03:17:59

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-13T23:17:31', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '44618428-044e-42cf-97d6-803c4060cdd7'	System	14 Aug 2020 03:17:59
User entered 'None (0)'	System	14 Aug 2020 03:17:59

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-13T23:17:43', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '44618428-044e-42cf-97d6-803c4060cdd7'	System	14 Aug 2020 03:17:59
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	14 Aug 2020 03:17:59

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-13T23:17:46', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '44618428-044e-42cf-97d6-803c4060cdd7'	System	14 Aug 2020 03:17:59
User entered 'None (0)'	System	14 Aug 2020 03:17:59

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-13T23:17:50', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '44618428-044e-42cf-97d6-803c4060cdd7'	System	14 Aug 2020 03:17:59
User entered 'No (N)'	System	14 Aug 2020 03:17:59

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-13T23:17:57', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '44618428-044e-42cf-97d6-803c4060cdd7'	System	14 Aug 2020 03:17:59
User entered '13 Aug 2020 23:17'	System	14 Aug 2020 03:17:59

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 4'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-14T18:32:40', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'daf8d2b4-baaf-48a2-a196-1ac911de372c'	System	14 Aug 2020 22:33:01
User entered 'None (0)'	System	14 Aug 2020 22:33:01

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-14T18:32:43', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'daf8d2b4-baaf-48a2-a196-1ac911de372c'	System	14 Aug 2020 22:33:01
User entered 'None (0)'	System	14 Aug 2020 22:33:01

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-14T18:32:46', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'daf8d2b4-baaf-48a2-a196-1ac911de372c'	System	14 Aug 2020 22:33:01
User entered 'None (0)'	System	14 Aug 2020 22:33:01

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-14T18:32:49', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'daf8d2b4-baaf-48a2-a196-1ac911de372c'	System	14 Aug 2020 22:33:01
User entered 'None (0)'	System	14 Aug 2020 22:33:01

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-14T18:32:51', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'daf8d2b4-baaf-48a2-a196-1ac911de372c'	System	14 Aug 2020 22:33:01
User entered 'None (0)'	System	14 Aug 2020 22:33:01

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-14T18:32:54', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'daf8d2b4-baaf-48a2-a196-1ac911de372c'	System	14 Aug 2020 22:33:01
User entered 'None (0)'	System	14 Aug 2020 22:33:01

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-14T18:32:57', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'daf8d2b4-baaf-48a2-a196-1ac911de372c'	System	14 Aug 2020 22:33:01
User entered 'No (N)'	System	14 Aug 2020 22:33:01

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-14T18:32:59', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'daf8d2b4-baaf-48a2-a196-1ac911de372c'	System	14 Aug 2020 22:33:01
User entered '14 Aug 2020 18:32'	System	14 Aug 2020 22:33:01

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 5'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-15T23:17:14', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '91dcdb3c-53bb-4245-9d19-7634f1dcf7bc'	System	16 Aug 2020 03:17:35
User entered 'None (0)'	System	16 Aug 2020 03:17:35

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-15T23:17:17', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '91dcdb3c-53bb-4245-9d19-7634f1dcf7bc'	System	16 Aug 2020 03:17:35
User entered 'None (0)'	System	16 Aug 2020 03:17:35

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-15T23:17:20', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '91dcdb3c-53bb-4245-9d19-7634f1dcf7bc'	System	16 Aug 2020 03:17:35
User entered 'None (0)'	System	16 Aug 2020 03:17:35

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-15T23:17:23', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '91dcdb3c-53bb-4245-9d19-7634f1dcf7bc'	System	16 Aug 2020 03:17:35
User entered 'None (0)'	System	16 Aug 2020 03:17:35

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-15T23:17:25', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '91dcdb3c-53bb-4245-9d19-7634f1dcf7bc'	System	16 Aug 2020 03:17:35
User entered 'None (0)'	System	16 Aug 2020 03:17:35

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-15T23:17:28', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '91dcdb3c-53bb-4245-9d19-7634f1dcf7bc'	System	16 Aug 2020 03:17:35
User entered 'None (0)'	System	16 Aug 2020 03:17:35

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-15T23:17:31', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '91dcdb3c-53bb-4245-9d19-7634f1dcf7bc'	System	16 Aug 2020 03:17:35
User entered 'No (N)'	System	16 Aug 2020 03:17:35

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-15T23:17:34', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '91dcdb3c-53bb-4245-9d19-7634f1dcf7bc'	System	16 Aug 2020 03:17:35
User entered '15 Aug 2020 23:17'	System	16 Aug 2020 03:17:35

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 6'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-16T22:59:08', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '5629cd0c-d5d5-4bd1-9d49-4d3e3b8b4143'	System	17 Aug 2020 02:59:31
User entered 'None (0)'	System	17 Aug 2020 02:59:31

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-16T22:59:11', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '5629cd0c-d5d5-4bd1-9d49-4d3e3b8b4143'	System	17 Aug 2020 02:59:31
User entered 'None (0)'	System	17 Aug 2020 02:59:31

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-16T22:59:14', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '5629cd0c-d5d5-4bd1-9d49-4d3e3b8b4143'	System	17 Aug 2020 02:59:31
User entered 'None (0)'	System	17 Aug 2020 02:59:31

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-16T22:59:17', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '5629cd0c-d5d5-4bd1-9d49-4d3e3b8b4143'	System	17 Aug 2020 02:59:31
User entered 'None (0)'	System	17 Aug 2020 02:59:31

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-16T22:59:19', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '5629cd0c-d5d5-4bd1-9d49-4d3e3b8b4143'	System	17 Aug 2020 02:59:31
User entered 'None (0)'	System	17 Aug 2020 02:59:31

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-16T22:59:22', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '5629cd0c-d5d5-4bd1-9d49-4d3e3b8b4143'	System	17 Aug 2020 02:59:31
User entered 'None (0)'	System	17 Aug 2020 02:59:31

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-16T22:59:24', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '5629cd0c-d5d5-4bd1-9d49-4d3e3b8b4143'	System	17 Aug 2020 02:59:31
User entered 'No (N)'	System	17 Aug 2020 02:59:31

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-16T22:59:27', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '5629cd0c-d5d5-4bd1-9d49-4d3e3b8b4143'	System	17 Aug 2020 02:59:31
User entered '16 Aug 2020 22:59'	System	17 Aug 2020 02:59:31

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 7'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-17T23:38:53', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '4e03f468-72ba-46b2-9932-b00e1e617b71'	System	18 Aug 2020 03:39:16
User entered 'None (0)'	System	18 Aug 2020 03:39:16

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-17T23:38:55', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '4e03f468-72ba-46b2-9932-b00e1e617b71'	System	18 Aug 2020 03:39:16
User entered 'None (0)'	System	18 Aug 2020 03:39:16

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-17T23:38:58', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '4e03f468-72ba-46b2-9932-b00e1e617b71'	System	18 Aug 2020 03:39:16
User entered 'None (0)'	System	18 Aug 2020 03:39:16

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-17T23:39:01', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '4e03f468-72ba-46b2-9932-b00e1e617b71'	System	18 Aug 2020 03:39:16
User entered 'None (0)'	System	18 Aug 2020 03:39:16

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-17T23:39:03', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '4e03f468-72ba-46b2-9932-b00e1e617b71'	System	18 Aug 2020 03:39:16
User entered 'None (0)'	System	18 Aug 2020 03:39:16

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-17T23:39:05', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '4e03f468-72ba-46b2-9932-b00e1e617b71'	System	18 Aug 2020 03:39:16
User entered 'None (0)'	System	18 Aug 2020 03:39:16

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-17T23:39:10', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '4e03f468-72ba-46b2-9932-b00e1e617b71'	System	18 Aug 2020 03:39:16
User entered 'No (N)'	System	18 Aug 2020 03:39:16

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-17T23:39:12', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '4e03f468-72ba-46b2-9932-b00e1e617b71'	System	18 Aug 2020 03:39:16
User entered '17 Aug 2020 23:39'	System	18 Aug 2020 03:39:16

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 02:59:06
User entered 'Day 8'	System	17 Aug 2020 02:59:06

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-18T23:19:14', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7dd8427f-ab71-4c8e-891c-79995f430dea'	System	19 Aug 2020 03:19:19
User entered 'None (1)'	System	19 Aug 2020 03:19:19

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 26 Nov 2020 09:26:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-18T23:19:17', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7dd8427f-ab71-4c8e-891c-79995f430dea'	System	19 Aug 2020 03:19:19
User entered '18 Aug 2020 23:19'	System	19 Aug 2020 03:19:19

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 02:59:06

US3432094

Folder: Diary Dose 1 (1)

Form: Injection Pain_Day(8)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 02:59:06

US3432094

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Aug 2020 02:59:06
User entered 'Day 8'	System	17 Aug 2020 02:59:06

US3432094

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-18T23:19:23', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '43f0ed70-624a-4c54-b67d-af517168e51b'	System	19 Aug 2020 03:19:29
User entered 'No (N)'	System	19 Aug 2020 03:19:29

US3432094

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:26:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-08-18T23:19:26', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '43f0ed70-624a-4c54-b67d-af517168e51b'	System	19 Aug 2020 03:19:29
User entered '18 Aug 2020 23:19'	System	19 Aug 2020 03:19:29

US3432094

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Aug 2020 12:00'	System	17 Aug 2020 02:59:06

US3432094

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Aug 2020 11:59'	System	17 Aug 2020 02:59:06

US3432094

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	18 Aug 2020 15:15:45

US3432094

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '18 Aug 2020'	Phoebe Cunningham (b) (4)	18 Aug 2020 15:15:45

US3432094

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	18 Aug 2020 15:15:45

US3432094

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	18 Aug 2020 15:15:45

US3432094

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	18 Aug 2020 15:15:53

US3432094

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:20

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 15:15:53

US3432094

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	25 Aug 2020 16:47:52

US3432094

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '25 Aug 2020'	Phoebe Cunningham (b) (4)	25 Aug 2020 16:47:52

US3432094

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	25 Aug 2020 16:47:52

US3432094

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	25 Aug 2020 16:47:52

US3432094

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	25 Aug 2020 16:47:56

US3432094

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:20

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Aug 2020 16:47:56

US3432094

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	01 Sep 2020 17:16:03

US3432094

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '1 Sep 2020'	Phoebe Cunningham (b) (4)	01 Sep 2020 17:16:03

US3432094

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	Phoebe Cunningham (b) (4)	01 Sep 2020 17:16:03

US3432094

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	Phoebe Cunningham (b) (4)	01 Sep 2020 17:16:03

US3432094

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Phoebe Cunningham (b) (4)	01 Sep 2020 17:16:07

US3432094

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:20

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Sep 2020 17:16:07

US3432094

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:26:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 14:07:50

US3432094

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 14:07:50

US3432094

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	10 Sep 2020 14:07:50

US3432094

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:26:20

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT2'	System	10 Sep 2020 14:07:50

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:20

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '9:06'	(b) (4), (b) (6)	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 9:06'	System	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:20

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '98.1' F	(b) (4), (b) (6)	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:20

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:20

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '53'	(b) (4), (b) (6)	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:20

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '14'	(b) (4), (b) (6)	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '142'	(b) (4), (b) (6)	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '64'	(b) (4), (b) (6)	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 26 Nov 2020 09:26:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:20

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 14:58:57
Query 'Data is required. Please provide.' answered by System data change (Site from System).		10 Sep 2020 14:58:57
User entered '10:35' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 14:58:57
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 14:58:21
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 10:35'	System	10 Sep 2020 14:58:57
User entered empty.	System	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:20

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '97.9' F	(b) (4), (b) (6)	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:20

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:20

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '48'	(b) (4), (b) (6)	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:20

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '18'	(b) (4), (b) (6)	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '146'	(b) (4), (b) (6)	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '67'	(b) (4), (b) (6)	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 26 Nov 2020 09:26:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	10 Sep 2020 14:58:21

US3432094

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 14:08:03

US3432094

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:20

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 14:08:03

US3432094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:26:20

[Was study treatment given?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 14:30:06

US3432094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:26:20

[If No, reason not given](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 14:30:06

US3432094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 14:30:06

US3432094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:26:20

[What was the study treatment?](#)

Audit	User	Time (GMT)
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 14:30:06

US3432094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:26:20

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 14:30:06

US3432094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '10:05'	(b) (4), (b) (6)	10 Sep 2020 14:30:06

US3432094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 10:05'	System	10 Sep 2020 14:30:06

US3432094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	10 Sep 2020 14:30:15
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered by data change (Site from System).	System	10 Sep 2020 14:30:15
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 14:30:15
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	10 Sep 2020 14:30:06
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	10 Sep 2020 14:30:06

US3432094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'ONCE'	System	10 Sep 2020 14:30:06

US3432094

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 14:30:06

US3432094

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 14:51:33

US3432094

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 10SEP2020, however this date is presently recorded for Visit 2 Day 29. Please clarify if the Unscheduled sample collected on 10SEP2020 is actually for Visit 2 Day 29 and update as appropriate.' answered with 'Updated on PPD.' (Site from DM).	Jun Bai Park Chang (b) (4)	10 Nov 2020 14:50:55
User opened query 'Per GCL Lab Reconciliation: Per GCL, there is an Unscheduled Immunogenicity Assessment with a Collection date of 10SEP2020, however this date is presently recorded for Visit 2 Day 29. Please clarify if the Unscheduled sample collected on 10SEP2020 is actually for Visit 2 Day 29 and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 19:25:14
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 14:51:33

US3432094

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '9:50'	(b) (4), (b) (6)	10 Sep 2020 14:51:33

US3432094

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '10 Sep 2020 9:50'	System	10 Sep 2020 14:51:33

US3432094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 26 Nov 2020 09:26:20

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 10SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' answered with 'Updated on PPD.' (Site from DM).	Jun Bai Park Chang (b) (4)	10 Nov 2020 14:50:46
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 10SEP2020 is recorded under Visit2 Day29 visit in EDC, however the same is reported under UNSCHEDULED visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 04:49:15
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 14:51:57

US3432094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:26:20

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	10 Sep 2020 14:51:57

US3432094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:26:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 14:51:57

US3432094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:26:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered '10:00'	(b) (4), (b) (6)	10 Sep 2020 14:51:57

US3432094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 26 Nov 2020 09:26:20

Collection date and time (derived)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 10SEP2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under UNSCHEDULED visit in GCL. Please reconcile the correct Visit and update if applicable. Else clarify, thank you.' (Site from DM). User entered '10 Sep 2020 10:00'	(b) (4), (b) (6)	22 Oct 2020 08:11:06
	System	10 Sep 2020 14:51:57

US3432094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:26:20

[Lab Test](#)

Audit	User	Time (GMT)
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	10 Sep 2020 14:51:57

US3432094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:26:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 14:51:57

US3432094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:26:20

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 14:51:57

US3432094

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 14:51:57

US3432094

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 14:30:22

US3432094

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:20

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Sep 2020 14:30:22

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T10:42:15', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '342f4d23-6d24-434a-82d6-7412636bb12b'	System	10 Sep 2020 14:42:36
User entered 'Yes (Y)'	System	10 Sep 2020 14:42:36

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T10:42:22', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '342f4d23-6d24-434a-82d6-7412636bb12b'	System	10 Sep 2020 14:42:36
User entered '97.9'	System	10 Sep 2020 14:42:36

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T10:42:26', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '342f4d23-6d24-434a-82d6-7412636bb12b'	System	10 Sep 2020 14:42:36
User entered 'No (N)'	System	10 Sep 2020 14:42:36

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T10:42:32', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '342f4d23-6d24-434a-82d6-7412636bb12b'	System	10 Sep 2020 14:42:36
User entered '10 Sep 2020 10:42'	System	10 Sep 2020 14:42:36

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 10:25'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:55'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T21:44:32', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'ea72b43e-1346-4580-b133-8be866113d81'	System	11 Sep 2020 01:44:56
User entered 'Yes (Y)'	System	11 Sep 2020 01:44:56

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T21:44:40', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'ea72b43e-1346-4580-b133-8be866113d81'	System	11 Sep 2020 01:44:56
User entered '97.6'	System	11 Sep 2020 01:44:56

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T21:44:44', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'ea72b43e-1346-4580-b133-8be866113d81'	System	11 Sep 2020 01:44:56
User entered 'No (N)'	System	11 Sep 2020 01:44:56

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T21:44:50', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'ea72b43e-1346-4580-b133-8be866113d81'	System	11 Sep 2020 01:44:56
User entered '10 Sep 2020 21:44'	System	11 Sep 2020 01:44:56

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 13:50'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 2'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:36:56', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '61b66ec0-c29a-4b24-979c-5d0d664c3713'	System	11 Sep 2020 22:37:31
User entered 'Yes (Y)'	System	11 Sep 2020 22:37:31

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:20

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:37:02', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '61b66ec0-c29a-4b24-979c-5d0d664c3713'	System	11 Sep 2020 22:37:31
User entered '98.3'	System	11 Sep 2020 22:37:31

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:37:06', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '61b66ec0-c29a-4b24-979c-5d0d664c3713'	System	11 Sep 2020 22:37:31
User entered 'Yes (Y)'	System	11 Sep 2020 22:37:31

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Updated' (Site from System).	(b) (4), (b) (6)	20 Oct 2020 06:00:36
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:37:12', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '61b66ec0-c29a-4b24-979c-5d0d664c3713'	Jun Bai Park Chang (b) (4)	05 Oct 2020 14:09:34
User entered '1'	System	11 Sep 2020 22:37:31

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:20

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:37:12', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '61b66ec0-c29a-4b24-979c-5d0d664c3713'	System	11 Sep 2020 22:37:31
User entered '0'	System	11 Sep 2020 22:37:31

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:37:19', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '61b66ec0-c29a-4b24-979c-5d0d664c3713'	System	11 Sep 2020 22:37:31
User entered '11 Sep 2020 18:37'	System	11 Sep 2020 22:37:31

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 3'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:29:18', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7750365f-12e0-4bb9-b4b1-3780c2140c37'	System	13 Sep 2020 02:29:45
User entered 'Yes (Y)'	System	13 Sep 2020 02:29:45

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:29:23', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7750365f-12e0-4bb9-b4b1-3780c2140c37'	System	13 Sep 2020 02:29:45
User entered '97.3'	System	13 Sep 2020 02:29:45

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:29:26', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7750365f-12e0-4bb9-b4b1-3780c2140c37'	System	13 Sep 2020 02:29:45
User entered 'Yes (Y)'	System	13 Sep 2020 02:29:45

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'updated' (Site from System).	(b) (4), (b) (6)	20 Oct 2020 06:00:41
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:29:37', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7750365f-12e0-4bb9-b4b1-3780c2140c37' User entered '1'	Jun Bai Park Chang (b) (4)	05 Oct 2020 14:09:42
	System	13 Sep 2020 02:29:45
	System	13 Sep 2020 02:29:45
	System	13 Sep 2020 02:29:45

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:20

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:29:37', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7750365f-12e0-4bb9-b4b1-3780c2140c37'	System	13 Sep 2020 02:29:45
User entered '0'	System	13 Sep 2020 02:29:45

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:29:41', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7750365f-12e0-4bb9-b4b1-3780c2140c37'	System	13 Sep 2020 02:29:45
User entered '12 Sep 2020 22:29'	System	13 Sep 2020 02:29:45

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 4'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T00:05:54', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '3a402447-bd9e-4025-b4e7-6111ce357b49'	System	14 Sep 2020 04:06:23
User entered 'Yes (Y)'	System	14 Sep 2020 04:06:23

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T00:06:00', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '3a402447-bd9e-4025-b4e7-6111ce357b49'	System	14 Sep 2020 04:06:23
User entered '96.8'	System	14 Sep 2020 04:06:23

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T00:06:13', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '3a402447-bd9e-4025-b4e7-6111ce357b49'	System	14 Sep 2020 04:06:23
User entered 'No (N)'	System	14 Sep 2020 04:06:23

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T00:06:20', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '3a402447-bd9e-4025-b4e7-6111ce357b49'	System	14 Sep 2020 04:06:23
User entered '14 Sep 2020 00:06'	System	14 Sep 2020 04:06:23

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 5'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T22:10:16', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'c0b941ea-79cc-4831-b94b-0069127d6959'	System	15 Sep 2020 02:10:33
User entered 'Yes (Y)'	System	15 Sep 2020 02:10:33

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:20

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T22:10:21', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'c0b941ea-79cc-4831-b94b-0069127d6959'	System	15 Sep 2020 02:10:33
User entered '97.8'	System	15 Sep 2020 02:10:33

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T22:10:26', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'c0b941ea-79cc-4831-b94b-0069127d6959'	System	15 Sep 2020 02:10:33
User entered 'No (N)'	System	15 Sep 2020 02:10:33

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T22:10:29', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'c0b941ea-79cc-4831-b94b-0069127d6959'	System	15 Sep 2020 02:10:33
User entered '14 Sep 2020 22:10'	System	15 Sep 2020 02:10:33

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 6'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-15T21:53:22', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'df380143-4c17-4347-aed0-c33e8ae3dc6b'	System	16 Sep 2020 01:53:35
User entered 'Yes (Y)'	System	16 Sep 2020 01:53:35

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-15T21:53:27', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'df380143-4c17-4347-aed0-c33e8ae3dc6b'	System	16 Sep 2020 01:53:35
User entered '97.5'	System	16 Sep 2020 01:53:35

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-15T21:53:30', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'df380143-4c17-4347-aed0-c33e8ae3dc6b'	System	16 Sep 2020 01:53:35
User entered 'No (N)'	System	16 Sep 2020 01:53:35

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-15T21:53:34', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'df380143-4c17-4347-aed0-c33e8ae3dc6b'	System	16 Sep 2020 01:53:35
User entered '15 Sep 2020 21:53'	System	16 Sep 2020 01:53:35

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 7'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:20

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T00:20:20', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'eea553bd-618f-4546-a2ca-a86230639499'	System	17 Sep 2020 04:20:37
User entered 'Yes (Y)'	System	17 Sep 2020 04:20:37

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:20

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T00:20:25', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'eea553bd-618f-4546-a2ca-a86230639499'	System	17 Sep 2020 04:20:37
User entered '96.9'	System	17 Sep 2020 04:20:37

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T00:20:28', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'eea553bd-618f-4546-a2ca-a86230639499'	System	17 Sep 2020 04:20:37
User entered 'No (N)'	System	17 Sep 2020 04:20:37

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T00:20:31', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'eea553bd-618f-4546-a2ca-a86230639499'	System	17 Sep 2020 04:20:37
User entered '17 Sep 2020 00:20'	System	17 Sep 2020 04:20:37

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T10:42:43', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '3f9a9025-6973-4aa7-8a13-6b451462724a'	System	10 Sep 2020 14:43:24
User entered 'None (1)'	System	10 Sep 2020 14:43:24

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T10:42:52', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '3f9a9025-6973-4aa7-8a13-6b451462724a' User entered 'No (N)'	System	10 Sep 2020 14:43:24
	System	10 Sep 2020 14:43:24

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T10:42:57', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '3f9a9025-6973-4aa7-8a13-6b451462724a' User entered 'No (N)'	System	10 Sep 2020 14:43:24

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T10:43:18', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '3f9a9025-6973-4aa7-8a13-6b451462724a' User entered 'None (1)'	System	10 Sep 2020 14:43:24
	System	10 Sep 2020 14:43:24

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T10:43:21', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '3f9a9025-6973-4aa7-8a13-6b451462724a' User entered '10 Sep 2020 10:43'	System	10 Sep 2020 14:43:24
	System	10 Sep 2020 14:43:24

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 10:25'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:55'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T21:45:02', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'e82599ba-2906-4c71-a964-c60b243f3ba0'	System	11 Sep 2020 01:45:36
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 01:45:36

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T21:45:06', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'e82599ba-2906-4c71-a964-c60b243f3ba0'	System	11 Sep 2020 01:45:36
User entered 'No (N)'	System	11 Sep 2020 01:45:36

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T21:45:09', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'e82599ba-2906-4c71-a964-c60b243f3ba0' User entered 'Yes (Y)'	System	11 Sep 2020 01:45:36
	System	11 Sep 2020 01:45:36

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T21:45:20', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'e82599ba-2906-4c71-a964-c60b243f3ba0' User entered '15'	System	11 Sep 2020 01:45:36
	System	11 Sep 2020 01:45:36

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T21:45:25', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'e82599ba-2906-4c71-a964-c60b243f3ba0'	System	11 Sep 2020 01:45:36
User entered 'None (1)'	System	11 Sep 2020 01:45:36

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T21:45:33', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'e82599ba-2906-4c71-a964-c60b243f3ba0'	System	11 Sep 2020 01:45:36
User entered '10 Sep 2020 21:45'	System	11 Sep 2020 01:45:36

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 13:50'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 2'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:37:41', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'f156dd06-7906-4ce2-a9f6-658ab876e3b3'	System	11 Sep 2020 22:38:51
User entered 'Any use of prescription pain reliever or System prevents daily activity (4)'		11 Sep 2020 22:38:51

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:37:44', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'f156dd06-7906-4ce2-a9f6-658ab876e3b3'	System	11 Sep 2020 22:38:51
User entered 'No (N)'	System	11 Sep 2020 22:38:51

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:37:48', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'f156dd06-7906-4ce2-a9f6-658ab876e3b3'	System	11 Sep 2020 22:38:51
User entered 'Yes (Y)'	System	11 Sep 2020 22:38:51

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:20

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:38:13', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'f156dd06-7906-4ce2-a9f6-658ab876e3b3' User entered '30'	System	11 Sep 2020 22:38:51
	System	11 Sep 2020 22:38:51

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:38:44', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'f156dd06-7906-4ce2-a9f6-658ab876e3b3'	System	11 Sep 2020 22:38:51
User entered 'Does not interfere with activity (2)'	System	11 Sep 2020 22:38:51

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:38:49', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'f156dd06-7906-4ce2-a9f6-658ab876e3b3'	System	11 Sep 2020 22:38:51
User entered '11 Sep 2020 18:38'	System	11 Sep 2020 22:38:51

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 3'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:30:16', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '82617e6d-e8e8-4f12-b38e-7d6717ceecfb'	System	13 Sep 2020 02:30:59
User entered 'Any use of prescription pain reliever or prevents daily activity (4)'	System	13 Sep 2020 02:30:59

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:30:19', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '82617e6d-e8e8-4f12-b38e-7d6717ceecfb'	System	13 Sep 2020 02:30:59
User entered 'No (N)'	System	13 Sep 2020 02:30:59

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:30:22', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '82617e6d-e8e8-4f12-b38e-7d6717ceecfb'	System	13 Sep 2020 02:30:59
User entered 'Yes (Y)'	System	13 Sep 2020 02:30:59

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:20

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:30:26', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '82617e6d-e8e8-4f12-b38e-7d6717ceecfb' User entered '40'	System	13 Sep 2020 02:30:59
	System	13 Sep 2020 02:30:59

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:30:53', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '82617e6d-e8e8-4f12-b38e-7d6717ceecfb'	System	13 Sep 2020 02:30:59
User entered 'Does not interfere with activity (2)'	System	13 Sep 2020 02:30:59

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:30:56', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '82617e6d-e8e8-4f12-b38e-7d6717ceecfb'	System	13 Sep 2020 02:30:59
User entered '12 Sep 2020 22:30'	System	13 Sep 2020 02:30:59

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 4'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T00:00:06', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'f1a363f5-ff2a-4c05-8320-f46c01fddc9a'	System	14 Sep 2020 04:00:57
User entered 'Any use of prescription pain reliever or prevents daily activity (4)'	System	14 Sep 2020 04:00:57

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T00:00:11', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'f1a363f5-ff2a-4c05-8320-f46c01fddc9a'	System	14 Sep 2020 04:00:57
User entered 'Yes (Y)'	System	14 Sep 2020 04:00:57

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:20

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

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T00:00:19', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'f1a363f5-ff2a-4c05-8320-f46c01fddc9a' User entered '50'	System	14 Sep 2020 04:00:57
	System	14 Sep 2020 04:00:57

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T00:00:23', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'f1a363f5-ff2a-4c05-8320-f46c01fddc9a'	System	14 Sep 2020 04:00:57
User entered 'Yes (Y)'	System	14 Sep 2020 04:00:57

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:20

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T00:00:28', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'f1a363f5-ff2a-4c05-8320-f46c01fddc9a' User entered '50'	System	14 Sep 2020 04:00:57
	System	14 Sep 2020 04:00:57

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T00:00:48', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'f1a363f5-ff2a-4c05-8320-f46c01fddc9a'	System	14 Sep 2020 04:00:57
User entered 'Does not interfere with activity (2)'	System	14 Sep 2020 04:00:57

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T00:00:52', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'f1a363f5-ff2a-4c05-8320-f46c01fddc9a'	System	14 Sep 2020 04:00:57
User entered '14 Sep 2020 00:00'	System	14 Sep 2020 04:00:57

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 5'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T22:11:20', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '353e86f3-8f7d-482a-9087-6b6aa4490784'	System	15 Sep 2020 02:12:24
User entered 'Does not interfere with activity (2)'	System	15 Sep 2020 02:12:24

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T22:11:23', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '353e86f3-8f7d-482a-9087-6b6aa4490784'	System	15 Sep 2020 02:12:24
User entered 'Yes (Y)'	System	15 Sep 2020 02:12:24

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:20

Please record - REDNESS AT INJECTION SITE (in mm)

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T22:11:27', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '353e86f3-8f7d-482a-9087-6b6aa4490784' User entered '50'	System	15 Sep 2020 02:12:24
	System	15 Sep 2020 02:12:24

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T22:11:31', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '353e86f3-8f7d-482a-9087-6b6aa4490784'	System	15 Sep 2020 02:12:24
User entered 'Yes (Y)'	System	15 Sep 2020 02:12:24

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:20

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T22:11:35', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '353e86f3-8f7d-482a-9087-6b6aa4490784' User entered '40'	System	15 Sep 2020 02:12:24
	System	15 Sep 2020 02:12:24

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T22:12:16', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '353e86f3-8f7d-482a-9087-6b6aa4490784'	System	15 Sep 2020 02:12:24
User entered 'Does not interfere with activity (2)'	System	15 Sep 2020 02:12:24

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T22:12:19', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '353e86f3-8f7d-482a-9087-6b6aa4490784'	System	15 Sep 2020 02:12:24
User entered '14 Sep 2020 22:12'	System	15 Sep 2020 02:12:24

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 6'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-15T21:53:43', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'b24ef376-919a-4f00-b11f-9e37f801b456'	System	16 Sep 2020 01:55:45
User entered 'Does not interfere with activity (2)'	System	16 Sep 2020 01:55:45

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-15T21:54:31', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'b24ef376-919a-4f00-b11f-9e37f801b456'	System	16 Sep 2020 01:55:45
User entered 'Yes (Y)'	System	16 Sep 2020 01:55:45

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:20

Please record - REDNESS AT INJECTION SITE (in mm)

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-15T21:54:44', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'b24ef376-919a-4f00-b11f-9e37f801b456' User entered '40'	System	16 Sep 2020 01:55:45
	System	16 Sep 2020 01:55:45

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-15T21:54:49', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'b24ef376-919a-4f00-b11f-9e37f801b456'	System	16 Sep 2020 01:55:45
User entered 'Yes (Y)'	System	16 Sep 2020 01:55:45

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:20

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-15T21:55:19', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'b24ef376-919a-4f00-b11f-9e37f801b456'	System	16 Sep 2020 01:55:45
User entered '40'	System	16 Sep 2020 01:55:45

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-15T21:55:37', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'b24ef376-919a-4f00-b11f-9e37f801b456'	System	16 Sep 2020 01:55:45
User entered 'Does not interfere with activity (2)'	System	16 Sep 2020 01:55:45

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-15T21:55:41', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'b24ef376-919a-4f00-b11f-9e37f801b456'	System	16 Sep 2020 01:55:45
User entered '15 Sep 2020 21:55'	System	16 Sep 2020 01:55:45

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 7'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T00:20:39', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '270e2091-47a1-4430-bda1-1f61cf0bc2cc'	System	17 Sep 2020 04:21:22
User entered 'Does not interfere with activity (2)'	System	17 Sep 2020 04:21:22

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:20

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T00:20:43', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '270e2091-47a1-4430-bda1-1f61cf0bc2cc'	System	17 Sep 2020 04:21:22
User entered 'No (N)'	System	17 Sep 2020 04:21:22

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T00:20:46', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '270e2091-47a1-4430-bda1-1f61cf0bc2cc'	System	17 Sep 2020 04:21:22
User entered 'Yes (Y)'	System	17 Sep 2020 04:21:22

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:20

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T00:20:50', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '270e2091-47a1-4430-bda1-1f61cf0bc2cc' User entered '15'	System	17 Sep 2020 04:21:22
	System	17 Sep 2020 04:21:22

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T00:21:16', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '270e2091-47a1-4430-bda1-1f61cf0bc2cc'	System	17 Sep 2020 04:21:22
User entered 'None (1)'	System	17 Sep 2020 04:21:22

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T00:21:20', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '270e2091-47a1-4430-bda1-1f61cf0bc2cc'	System	17 Sep 2020 04:21:22
User entered '17 Sep 2020 00:21'	System	17 Sep 2020 04:21:22

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T10:43:26', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '0ed92ae5-2611-493f-b1c8-567ba07166af'	System	10 Sep 2020 14:43:48
User entered 'None (0)'	System	10 Sep 2020 14:43:48

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T10:43:28', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '0ed92ae5-2611-493f-b1c8-567ba07166af' User entered 'None (0)'	System	10 Sep 2020 14:43:48
	System	10 Sep 2020 14:43:48

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T10:43:32', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '0ed92ae5-2611-493f-b1c8-567ba07166af' User entered 'None (0)'	System	10 Sep 2020 14:43:48
	System	10 Sep 2020 14:43:48

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T10:43:34', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '0ed92ae5-2611-493f-b1c8-567ba07166af' User entered 'None (0)'	System	10 Sep 2020 14:43:48
	System	10 Sep 2020 14:43:48

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T10:43:36', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '0ed92ae5-2611-493f-b1c8-567ba07166af'	System	10 Sep 2020 14:43:48
User entered 'None (0)'	System	10 Sep 2020 14:43:48

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T10:43:39', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '0ed92ae5-2611-493f-b1c8-567ba07166af' User entered 'None (0)'	System	10 Sep 2020 14:43:48
	System	10 Sep 2020 14:43:48

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T10:43:42', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '0ed92ae5-2611-493f-b1c8-567ba07166af' User entered 'No (N)'	System	10 Sep 2020 14:43:48

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T10:43:45', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '0ed92ae5-2611-493f-b1c8-567ba07166af' User entered '10 Sep 2020 10:43'	System	10 Sep 2020 14:43:48
	System	10 Sep 2020 14:43:48

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 10:25'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 12:55'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T21:45:38', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '6ee701ae-4d15-4788-b556-f88d9311c298'	System	11 Sep 2020 01:46:07
User entered 'None (0)'	System	11 Sep 2020 01:46:07

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T21:45:42', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '6ee701ae-4d15-4788-b556-f88d9311c298'	System	11 Sep 2020 01:46:07
User entered 'No interference with activity (1)'	System	11 Sep 2020 01:46:07

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T21:45:45', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '6ee701ae-4d15-4788-b556-f88d9311c298'	System	11 Sep 2020 01:46:07
User entered 'None (0)'	System	11 Sep 2020 01:46:07

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T21:45:49', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '6ee701ae-4d15-4788-b556-f88d9311c298'	System	11 Sep 2020 01:46:07
User entered 'None (0)'	System	11 Sep 2020 01:46:07

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T21:45:51', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '6ee701ae-4d15-4788-b556-f88d9311c298'	System	11 Sep 2020 01:46:07
User entered 'None (0)'	System	11 Sep 2020 01:46:07

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T21:45:54', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '6ee701ae-4d15-4788-b556-f88d9311c298'	System	11 Sep 2020 01:46:07
User entered 'None (0)'	System	11 Sep 2020 01:46:07

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T21:45:58', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '6ee701ae-4d15-4788-b556-f88d9311c298'	System	11 Sep 2020 01:46:07
User entered 'No (N)'	System	11 Sep 2020 01:46:07

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-10T21:46:01', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '6ee701ae-4d15-4788-b556-f88d9311c298'	System	11 Sep 2020 01:46:07
User entered '10 Sep 2020 21:46'	System	11 Sep 2020 01:46:07

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '10 Sep 2020 13:50'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 2'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:38:56', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'dffde861-d499-457b-a06e-e89f5d968609'	System	11 Sep 2020 22:39:28
User entered 'No interference with activity (1)'	System	11 Sep 2020 22:39:28

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:39:02', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'dffde861-d499-457b-a06e-e89f5d968609'	System	11 Sep 2020 22:39:28
User entered 'Some interference with activity (2)'	System	11 Sep 2020 22:39:28

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:39:06', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'dffde861-d499-457b-a06e-e89f5d968609'	System	11 Sep 2020 22:39:28
User entered 'None (0)'	System	11 Sep 2020 22:39:28

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:39:09', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'dffde861-d499-457b-a06e-e89f5d968609'	System	11 Sep 2020 22:39:28
User entered 'None (0)'	System	11 Sep 2020 22:39:28

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:39:17', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'dffde861-d499-457b-a06e-e89f5d968609'	System	11 Sep 2020 22:39:28
User entered 'None (0)'	System	11 Sep 2020 22:39:28

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:39:19', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'dffde861-d499-457b-a06e-e89f5d968609'	System	11 Sep 2020 22:39:28
User entered 'None (0)'	System	11 Sep 2020 22:39:28

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:39:23', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'dffde861-d499-457b-a06e-e89f5d968609'	System	11 Sep 2020 22:39:28
User entered 'No (N)'	System	11 Sep 2020 22:39:28

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-11T18:39:25', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'dffde861-d499-457b-a06e-e89f5d968609'	System	11 Sep 2020 22:39:28
User entered '11 Sep 2020 18:39'	System	11 Sep 2020 22:39:28

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 3'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:31:06', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '14fc510d-9101-447d-ae26-e0cb7381253c'	System	13 Sep 2020 02:31:33
User entered 'None (0)'	System	13 Sep 2020 02:31:33

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:31:12', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '14fc510d-9101-447d-ae26-e0cb7381253c'	System	13 Sep 2020 02:31:33
User entered 'Some interference with activity (2)'	System	13 Sep 2020 02:31:33

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:31:16', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '14fc510d-9101-447d-ae26-e0cb7381253c'	System	13 Sep 2020 02:31:33
User entered 'None (0)'	System	13 Sep 2020 02:31:33

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:31:19', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '14fc510d-9101-447d-ae26-e0cb7381253c' User entered 'None (0)'	System	13 Sep 2020 02:31:33
	System	13 Sep 2020 02:31:33

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:31:22', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '14fc510d-9101-447d-ae26-e0cb7381253c'	System	13 Sep 2020 02:31:33
User entered 'None (0)'	System	13 Sep 2020 02:31:33

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:31:24', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '14fc510d-9101-447d-ae26-e0cb7381253c'	System	13 Sep 2020 02:31:33
User entered 'None (0)'	System	13 Sep 2020 02:31:33

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:31:27', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '14fc510d-9101-447d-ae26-e0cb7381253c'	System	13 Sep 2020 02:31:33
User entered 'No (N)'	System	13 Sep 2020 02:31:33

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-12T22:31:30', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '14fc510d-9101-447d-ae26-e0cb7381253c'	System	13 Sep 2020 02:31:33
User entered '12 Sep 2020 22:31'	System	13 Sep 2020 02:31:33

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 4'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T00:01:00', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'e765ac98-58ab-4652-b172-d967bec6f48e'	System	14 Sep 2020 04:01:30
User entered 'No interference with activity (1)'	System	14 Sep 2020 04:01:30

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T00:01:07', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'e765ac98-58ab-4652-b172-d967bec6f48e'	System	14 Sep 2020 04:01:30
User entered 'Significant; prevents daily activity (3)'	System	14 Sep 2020 04:01:30

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T00:01:11', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'e765ac98-58ab-4652-b172-d967bec6f48e'	System	14 Sep 2020 04:01:30
User entered 'None (0)'	System	14 Sep 2020 04:01:30

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T00:01:14', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'e765ac98-58ab-4652-b172-d967bec6f48e'	System	14 Sep 2020 04:01:30
User entered 'None (0)'	System	14 Sep 2020 04:01:30

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T00:01:17', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'e765ac98-58ab-4652-b172-d967bec6f48e'	System	14 Sep 2020 04:01:30
User entered 'None (0)'	System	14 Sep 2020 04:01:30

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T00:01:20', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'e765ac98-58ab-4652-b172-d967bec6f48e'	System	14 Sep 2020 04:01:30
User entered 'None (0)'	System	14 Sep 2020 04:01:30

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T00:01:24', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'e765ac98-58ab-4652-b172-d967bec6f48e'	System	14 Sep 2020 04:01:30
User entered 'No (N)'	System	14 Sep 2020 04:01:30

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T00:01:28', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'e765ac98-58ab-4652-b172-d967bec6f48e'	System	14 Sep 2020 04:01:30
User entered '14 Sep 2020 00:01'	System	14 Sep 2020 04:01:30

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 5'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T22:12:24', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '810cafba-1c47-4434-87eb-53ef6269c97a'	System	15 Sep 2020 02:12:50
User entered 'None (0)'	System	15 Sep 2020 02:12:50

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T22:12:28', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '810cafba-1c47-4434-87eb-53ef6269c97a'	System	15 Sep 2020 02:12:50
User entered 'Some interference with activity (2)'	System	15 Sep 2020 02:12:50

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T22:12:31', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '810cafba-1c47-4434-87eb-53ef6269c97a'	System	15 Sep 2020 02:12:50
User entered 'None (0)'	System	15 Sep 2020 02:12:50

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T22:12:34', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '810cafba-1c47-4434-87eb-53ef6269c97a'	System	15 Sep 2020 02:12:50
User entered 'None (0)'	System	15 Sep 2020 02:12:50

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T22:12:37', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '810cafba-1c47-4434-87eb-53ef6269c97a'	System	15 Sep 2020 02:12:50
User entered 'None (0)'	System	15 Sep 2020 02:12:50

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T22:12:39', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '810cafba-1c47-4434-87eb-53ef6269c97a'	System	15 Sep 2020 02:12:50
User entered 'None (0)'	System	15 Sep 2020 02:12:50

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T22:12:42', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '810cafba-1c47-4434-87eb-53ef6269c97a'	System	15 Sep 2020 02:12:50
User entered 'No (N)'	System	15 Sep 2020 02:12:50

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-14T22:12:45', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '810cafba-1c47-4434-87eb-53ef6269c97a'	System	15 Sep 2020 02:12:50
User entered '14 Sep 2020 22:12'	System	15 Sep 2020 02:12:50

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 6'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-15T21:55:45', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '019d12a3-b0f8-437d-aa4a-b70c089b102f'	System	16 Sep 2020 01:56:09
User entered 'None (0)'	System	16 Sep 2020 01:56:09

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-15T21:55:50', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '019d12a3-b0f8-437d-aa4a-b70c089b102f'	System	16 Sep 2020 01:56:09
User entered 'No interference with activity (1)'	System	16 Sep 2020 01:56:09

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-15T21:55:53', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '019d12a3-b0f8-437d-aa4a-b70c089b102f'	System	16 Sep 2020 01:56:09
User entered 'None (0)'	System	16 Sep 2020 01:56:09

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-15T21:55:56', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '019d12a3-b0f8-437d-aa4a-b70c089b102f'	System	16 Sep 2020 01:56:09
User entered 'None (0)'	System	16 Sep 2020 01:56:09

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-15T21:55:58', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '019d12a3-b0f8-437d-aa4a-b70c089b102f'	System	16 Sep 2020 01:56:09
User entered 'None (0)'	System	16 Sep 2020 01:56:09

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-15T21:56:00', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '019d12a3-b0f8-437d-aa4a-b70c089b102f'	System	16 Sep 2020 01:56:09
User entered 'None (0)'	System	16 Sep 2020 01:56:09

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-15T21:56:03', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '019d12a3-b0f8-437d-aa4a-b70c089b102f'	System	16 Sep 2020 01:56:09
User entered 'No (N)'	System	16 Sep 2020 01:56:09

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-15T21:56:04', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '019d12a3-b0f8-437d-aa4a-b70c089b102f'	System	16 Sep 2020 01:56:09
User entered '15 Sep 2020 21:56'	System	16 Sep 2020 01:56:09

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	10 Sep 2020 14:30:06
User entered 'Day 7'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:20

HEADACHE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T00:21:24', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7c24e40f-a3b5-4344-a5da-550dbd314658'	System	17 Sep 2020 04:21:43
User entered 'None (0)'	System	17 Sep 2020 04:21:43

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:20

FATIGUE

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T00:21:27', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7c24e40f-a3b5-4344-a5da-550dbd314658'	System	17 Sep 2020 04:21:43
User entered 'No interference with activity (1)'	System	17 Sep 2020 04:21:43

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:20

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T00:21:30', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7c24e40f-a3b5-4344-a5da-550dbd314658'	System	17 Sep 2020 04:21:43
User entered 'None (0)'	System	17 Sep 2020 04:21:43

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:20

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T00:21:32', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7c24e40f-a3b5-4344-a5da-550dbd314658'	System	17 Sep 2020 04:21:43
User entered 'None (0)'	System	17 Sep 2020 04:21:43

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:20

NAUSEA/VOMITING

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T00:21:35', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7c24e40f-a3b5-4344-a5da-550dbd314658'	System	17 Sep 2020 04:21:43
User entered 'None (0)'	System	17 Sep 2020 04:21:43

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:20

CHILLS

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T00:21:37', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7c24e40f-a3b5-4344-a5da-550dbd314658' User entered 'None (0)'	System	17 Sep 2020 04:21:43
	System	17 Sep 2020 04:21:43

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T00:21:40', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7c24e40f-a3b5-4344-a5da-550dbd314658'	System	17 Sep 2020 04:21:43
User entered 'No (N)'	System	17 Sep 2020 04:21:43

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T00:21:41', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '7c24e40f-a3b5-4344-a5da-550dbd314658' User entered '17 Sep 2020 00:21'	System	17 Sep 2020 04:21:43
	System	17 Sep 2020 04:21:43

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 14:30:06

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 01:55:45
User entered 'Day 8'	System	16 Sep 2020 01:55:45

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T20:09:34', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '238bb030-e062-4d6f-ad2f-0f5f8c27f0df'	System	18 Sep 2020 00:09:43
User entered 'Does not interfere with activity (2)'	System	18 Sep 2020 00:09:43

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 26 Nov 2020 09:26:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T20:09:38', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '238bb030-e062-4d6f-ad2f-0f5f8c27f0df'	System	18 Sep 2020 00:09:43
User entered '17 Sep 2020 20:09'	System	18 Sep 2020 00:09:43

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 01:55:45

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 01:55:45

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(9)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 04:21:22
User entered 'Day 9'	System	17 Sep 2020 04:21:22

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(9)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 04:21:22

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(9)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 04:21:22

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(10)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Sep 2020 00:09:43
User entered 'Day 10'	System	18 Sep 2020 00:09:43

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(10)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 00:09:43

US3432094

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(10)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 00:09:43

US3432094

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 01:55:45
User entered 'Day 8'	System	16 Sep 2020 01:55:45

US3432094

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T20:10:13', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '6f64ed98-1be6-4334-ba99-c0224f463fcf'	System	18 Sep 2020 00:10:25
User entered 'Yes (Y)'	System	18 Sep 2020 00:10:25

US3432094

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 26 Nov 2020 09:26:20

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T20:10:17', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '6f64ed98-1be6-4334-ba99-c0224f463fcf' User entered '10'	System	18 Sep 2020 00:10:25
	System	18 Sep 2020 00:10:25

US3432094

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 26 Nov 2020 09:26:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T20:10:21', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '6f64ed98-1be6-4334-ba99-c0224f463fcf'	System	18 Sep 2020 00:10:25
User entered '17 Sep 2020 20:10'	System	18 Sep 2020 00:10:25

US3432094

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 01:55:45

US3432094

Folder: Diary Dose 2 (1)

Form: Swelling_Day(8)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 01:55:45

US3432094

Folder: Diary Dose 2 (1)

Form: Swelling_Day(9)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 04:21:22
User entered 'Day 9'	System	17 Sep 2020 04:21:22

US3432094

Folder: Diary Dose 2 (1)

Form: Swelling_Day(9)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 04:21:22

US3432094

Folder: Diary Dose 2 (1)

Form: Swelling_Day(9)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 04:21:22

US3432094

Folder: Diary Dose 2 (1)

Form: Swelling_Day(10)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Sep 2020 00:10:25
User entered 'Day 10'	System	18 Sep 2020 00:10:25

US3432094

Folder: Diary Dose 2 (1)

Form: Swelling_Day(10)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 00:10:25

US3432094

Folder: Diary Dose 2 (1)

Form: Swelling_Day(10)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 00:10:25

US3432094

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 01:56:09
User entered 'Day 8'	System	16 Sep 2020 01:56:09

US3432094

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T20:10:29', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '5a69b1cf-8911-438b-8335-d776b8778cb8'	System	18 Sep 2020 00:10:34
User entered 'None (0)'	System	18 Sep 2020 00:10:34

US3432094

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:26:20

[PC Time Stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T20:10:31', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '5a69b1cf-8911-438b-8335-d776b8778cb8'	System	18 Sep 2020 00:10:34
User entered '17 Sep 2020 20:10'	System	18 Sep 2020 00:10:34

US3432094

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 01:56:09

US3432094

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 01:56:09

US3432094

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	16 Sep 2020 01:55:45
User entered 'Day 8'	System	16 Sep 2020 01:55:45

US3432094

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T20:10:35', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '2dca7b66-888c-41d3-a9fd-1e1b373f3460'	System	18 Sep 2020 00:10:40
User entered 'No (N)'	System	18 Sep 2020 00:10:40

US3432094

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:26:20

[PC Time stamp](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-09-17T20:10:38', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '2dca7b66-888c-41d3-a9fd-1e1b373f3460'	System	18 Sep 2020 00:10:40
User entered '17 Sep 2020 20:10'	System	18 Sep 2020 00:10:40

US3432094

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 01:55:45

US3432094

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 01:55:45

US3432094

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	17 Sep 2020 04:21:22
User entered 'Day 9'	System	17 Sep 2020 04:21:22

US3432094

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 04:21:22

US3432094

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 04:21:22

US3432094

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	18 Sep 2020 00:09:43
User entered 'Day 10'	System	18 Sep 2020 00:09:43

US3432094

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:26:20

[PC Open Date & Time](#)

Audit	User	Time (GMT)
User entered '19 Sep 2020 12:00'	System	18 Sep 2020 00:09:43

US3432094

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(10)

Generated On: 26 Nov 2020 09:26:20

[PC Close Date & Time](#)

Audit	User	Time (GMT)
User entered '20 Sep 2020 11:59'	System	18 Sep 2020 00:09:43

US3432094

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 17:13:49

US3432094

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:20

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '17 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 17:13:49

US3432094

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:20

[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 17:13:49

US3432094

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 17:13:49

US3432094

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 17:13:56

US3432094

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:20

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Sep 2020 17:13:56

US3432094

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 17:15:03

US3432094

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:20

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 17:15:03

US3432094

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:20

[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 17:15:03

US3432094

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 17:15:03

US3432094

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 14:14:35

US3432094

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:20

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 14:14:35

US3432094

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 14:17:08

US3432094

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:20

[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 14:17:08

US3432094

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:20

[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 14:17:08

US3432094

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 14:17:08

US3432094

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 14:17:12

US3432094

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:20

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Oct 2020 14:17:12

US3432094

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:26:20

[Was this visit performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 17:40:54

US3432094

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '8 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 17:40:54

US3432094

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	08 Oct 2020 17:40:54

US3432094

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 26 Nov 2020 09:26:20

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	08 Oct 2020 17:40:54

US3432094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:20

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 17:41:37

US3432094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:20

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '8 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 17:41:37

US3432094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '09:54'	(b) (4), (b) (6)	08 Oct 2020 17:41:37

US3432094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '8 Oct 2020 09:54'	System	08 Oct 2020 17:41:37

US3432094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:20

Temperature (xxx.x)

Audit	User	Time (GMT)
User entered '037.0' C	(b) (4), (b) (6)	08 Oct 2020 17:41:37

US3432094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:20

[Route of measurement](#)

Audit	User	Time (GMT)
User entered 'Oral (Oral)'	(b) (4), (b) (6)	08 Oct 2020 17:41:37

US3432094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:20

[If Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	08 Oct 2020 17:41:37

US3432094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:20

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User entered '047'	(b) (4), (b) (6)	08 Oct 2020 17:41:37

US3432094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:20

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Oct 2020 17:41:37

US3432094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '014'	(b) (4), (b) (6)	08 Oct 2020 17:41:37

US3432094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:20

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Oct 2020 17:41:37

US3432094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:20

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '136'	(b) (4), (b) (6)	08 Oct 2020 17:41:37

US3432094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:20

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Oct 2020 17:41:37

US3432094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:20

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User entered '067'	(b) (4), (b) (6)	08 Oct 2020 17:41:37

US3432094

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 26 Nov 2020 09:26:20

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Oct 2020 17:41:37

US3432094

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:20

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 17:42:03

US3432094

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 26 Nov 2020 09:26:20

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '8 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 17:42:03

US3432094

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:20

[Was the sample collected?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 17:42:14

US3432094

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:20

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '8 Oct 2020'	(b) (4), (b) (6)	08 Oct 2020 17:42:14

US3432094

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:20

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User entered '09:58'	(b) (4), (b) (6)	08 Oct 2020 17:42:14

US3432094

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '8 Oct 2020 09:58'	System	08 Oct 2020 17:42:14

US3432094

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Oct 2020 17:42:17

US3432094

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:20

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Oct 2020 17:42:17

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 64'	System	11 Aug 2020 19:45:55

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-10-13T12:08:20', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '5233480e-f819-476d-82e5-7ef08a126599'	System	13 Oct 2020 16:08:34
User entered 'No (N)'	System	13 Oct 2020 16:08:34

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

Have you been exposed to someone with 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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-10-13T12:08:23', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '5233480e-f819-476d-82e5-7ef08a126599'	System	13 Oct 2020 16:08:34
User entered 'No (N)'	System	13 Oct 2020 16:08:34

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-10-13T12:08:30', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: '5233480e-f819-476d-82e5-7ef08a126599' User entered '13 Oct 2020 12:08:30'	System	13 Oct 2020 16:08:34
	System	13 Oct 2020 16:08:34

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:45:55
User entered '11 Oct 2020 00:01'	System	11 Aug 2020 19:45:55

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:45:55
User entered '15 Oct 2020 23:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 71'	System	11 Aug 2020 19:45:55

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-10-20T12:04:40', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'd19a2ab5-7ed8-412b-91fc-f768567dac2c'	System	20 Oct 2020 16:05:23
User entered 'No (N)'	System	20 Oct 2020 16:05:23

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

Have you been exposed to someone with 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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-10-20T12:04:44', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'd19a2ab5-7ed8-412b-91fc-f768567dac2c'	System	20 Oct 2020 16:05:23
User entered 'No (N)'	System	20 Oct 2020 16:05:23

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-10-20T12:04:48', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'd19a2ab5-7ed8-412b-91fc-f768567dac2c' User entered '20 Oct 2020 12:04:48'	System	20 Oct 2020 16:05:23
	System	20 Oct 2020 16:05:23

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:45:55
User entered '18 Oct 2020 00:01'	System	11 Aug 2020 19:45:55

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:45:55
User entered '22 Oct 2020 23:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 78'	System	11 Aug 2020 19:45:55

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-10-29T12:08:12', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'a85f9424-f26a-45e3-8753-a6d8c786538c'	System	29 Oct 2020 16:08:57
User entered 'Yes (Y)'	System	29 Oct 2020 16:08:57

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

Have you been exposed to someone with 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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-10-29T12:08:19', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'a85f9424-f26a-45e3-8753-a6d8c786538c'	System	29 Oct 2020 16:08:57
User entered 'No (N)'	System	29 Oct 2020 16:08:57

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-10-29T12:08:23', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'a85f9424-f26a-45e3-8753-a6d8c786538c'	System	29 Oct 2020 16:08:57
User entered 'No (N)'	System	29 Oct 2020 16:08:57

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-10-29T12:08:31', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'a85f9424-f26a-45e3-8753-a6d8c786538c'	System	29 Oct 2020 16:08:57
User entered 'Yes (Y)'	System	29 Oct 2020 16:08:57

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-10-29T12:08:38', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'a85f9424-f26a-45e3-8753-a6d8c786538c'	System	29 Oct 2020 16:08:57
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Oct 2020 16:08:57

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-10-29T12:08:46', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'a85f9424-f26a-45e3-8753-a6d8c786538c' User entered '29 Oct 2020 12:08:46'	System	29 Oct 2020 16:08:57
	System	29 Oct 2020 16:08:57

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:45:55
User entered '25 Oct 2020 00:01'	System	11 Aug 2020 19:45:55

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:45:55
User entered '29 Oct 2020 23:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:45:55
User entered 'Day 92'	System	11 Aug 2020 19:45:55

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-11-11T12:36:24', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'b3462f2a-f788-40db-b71b-7b513d195c73'	System	11 Nov 2020 17:36:40
User entered 'No (N)'	System	11 Nov 2020 17:36:40

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

Have you been exposed to someone with 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 (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-11-11T12:36:30', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'b3462f2a-f788-40db-b71b-7b513d195c73'	System	11 Nov 2020 17:36:40
User entered 'No (N)'	System	11 Nov 2020 17:36:40

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6134A79D-522E-4A17-AE24-0B45E817E1DD)', Time: '2020-11-11T12:36:35', User OID: 'PatientReportedOutcome (US3432094)', ODM File OID: 'b3462f2a-f788-40db-b71b-7b513d195c73' User entered '11 Nov 2020 12:36:35'	System	11 Nov 2020 17:36:40
	System	11 Nov 2020 17:36:40

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:45:55
User entered '08 Nov 2020 00:01'	System	11 Aug 2020 19:45:55

US3432094

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data entry locked.	System	11 Aug 2020 19:45:55
User entered '12 Nov 2020 23:59'	System	11 Aug 2020 19:45:55

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 61'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '08 Oct 2020 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '12 Oct 2020 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 68'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '15 Oct 2020 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '19 Oct 2020 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 75'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '22 Oct 2020 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '26 Oct 2020 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '29 Oct 2020 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '02 Nov 2020 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '05 Nov 2020 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '09 Nov 2020 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '12 Nov 2020 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '16 Nov 2020 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[TIMEPOINT](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 04:00:05

US3432094

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 26 Nov 2020 09:26:20

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 04:00:05
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 04:00:05

US3432094

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:20

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 15:59:12

US3432094

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '3 Nov 2020'	(b) (4), (b) (6)	03 Nov 2020 15:59:12

US3432094

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:20

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	03 Nov 2020 15:59:12

US3432094

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 26 Nov 2020 09:26:20

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	03 Nov 2020 15:59:12

US3432094

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	03 Nov 2020 15:59:18

US3432094

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 26 Nov 2020 09:26:20

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	03 Nov 2020 15:59:18

US3432094

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 26 Nov 2020 09:26:20

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 17:15:38

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:20

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Arthropod bite, LLT: Arthropod bite - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 20:36:40
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Sep 2020 20:36:40
Data point term sent to Coder	System	10 Sep 2020 17:18:04
User entered 'Insect Bite'	(b) (4), (b) (6) (b) (4)	10 Sep 2020 17:17:29

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' canceled (Site from System).	(b) (4), (b) (6)	12 Sep 2020 16:06:36
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	10 Sep 2020 17:17:29
User entered '7 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:17:29

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:17:29

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:20

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	01 Oct 2020 17:26:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Oct 2020 21:15:59
User entered '14 Sep 2020' reason for change: New Information	Natalie Izaguirre (b) (4)	08 Oct 2020 21:15:59
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Oct 2020 17:27:06
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Oct 2020 17:27:06
User entered 'un Sep 2020' (non-conformant).	(b) (4), (b) (6)	01 Oct 2020 17:27:06
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Oct 2020 17:26:58
User entered ' Sep 2020' (non-conformant).	(b) (4), (b) (6)	01 Oct 2020 17:26:58
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:17:29

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:20

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:17:29

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:20

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:17:29

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:20

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:20

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:20

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:20

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:17:29

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:20

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:17:29

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:20

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:17:29

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:20

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:17:29

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:20

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:20

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:20

[None](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:20

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	01 Oct 2020 17:26:58
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	10 Sep 2020 17:17:29

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:20

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:17:29

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:20

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:17:29

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:20

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	10 Sep 2020 17:17:29

US3432094

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 26 Nov 2020 09:26:20

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Sep 2020 17:17:29

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:20

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 16:13:35
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 16:13:35
Data point term sent to Coder	System	24 Nov 2020 16:12:51
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 16:12:20
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Nov 2020 16:12:20
Query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' canceled (Site from System).	Coder Import (b) (4) (b) (4)	24 Nov 2020 16:12:17
User opened query 'For coding purposes, please split to report each event separately (one event per line) to capture coding for all terms. ' (Site from System).	Coder Import (b) (4) (b) (4)	12 Nov 2020 22:42:43
User closed query 'Per DM CLR: Please review and specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	06 Nov 2020 04:12:41
Data point term sent to Coder	System	03 Nov 2020 16:06:50
User entered 'IPSI LATERAL LYMPHADENOPATHY (RIGHT POSTERIOR CERVICAL CHAIN, RIGHT POSTERIOR MANDIBULAR, RIGHT SUPRACLAVICULAR)' reason for change: Per Query Resolution	(b) (4), (b) (6) (b) (4), (b) (6)	03 Nov 2020 16:06:30
Query 'Per DM CLR: Please review and specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. ' answered with 'Condition has been updated as ipsilateral, same side as vaccination' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	03 Nov 2020 16:06:02
Data point term sent to Coder	System	03 Nov 2020 16:05:49

v6.020 DTW (1102)

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:20

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'LYMPHADENOPATHY (RIGHT POSTERIOR CERVICAL CHAIN, RIGHT POSTERIOR MANDIBULAR, RIGHT SUPRACLAVICULAR) - IPSILATERAL TO VACCINATION SITE' reason for change: Per Query Resolution Coding entries removed.	(b) (4), (b) (6)	03 Nov 2020 16:05:18
User entered 'LYMPHADENOPATHY (RIGHT POSTERIOR CERVICAL CHAIN, RIGHT POSTERIOR MANDIBULAR, RIGHT SUPRACLAVICULAR) - ipsilateral to vaxx site' reason for change: Per Query Resolution	(b) (4), (b) (6)	03 Nov 2020 16:04:57
User opened query 'Per DM CLR: Please review and specify the laterality of this condition (eg, ipsilateral-same side of vaccination site or contralateral-opposite side of vaccination site). Update accordingly. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 01:56:18
User closed query 'Per DM CLR: Please specify the location of LYMPHADENOPATHY (e.g., Both Axillas, Right Groin, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 17:54:34
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 07:21:17
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Oct 2020 07:21:17
Data point term sent to Coder	System	08 Oct 2020 22:43:43
Query 'Per DM CLR: Please specify the location of LYMPHADENOPATHY (e.g., Both Axillas, Right Groin, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	Natalie Izaguirre (b) (4)	08 Oct 2020 22:43:20

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:20

[Adverse event](#)

Audit	User	Time (GMT)
Coding entries removed.	Natalie Izaguirre (b) (4)	08 Oct 2020 22:43:10
User entered 'LYMPHADENOPATHY (right posterior cervical chain, right posterior mandibular, right supraclavicular)' reason for change: Data Entry Error	Natalie Izaguirre (b) (4)	08 Oct 2020 22:43:10
User opened query 'Per DM CLR: Please specify the location of LYMPHADENOPATHY (e.g., Both Axillas, Right Groin, etc). Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 08:31:58
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Spleen, lymphatic and reticuloendothelial system disorders, HLT: Lymphatic system disorders NEC, PT: Lymphadenopathy, LLT: Lymphadenopathy - version MedDRA\23.0.	Coder Import (b) (4)	10 Sep 2020 17:20:43
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Sep 2020 17:20:43
	(b) (4)	
Data point term sent to Coder	System	10 Sep 2020 17:19:06
User entered 'Lymphadenopathy'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	11 Sep 2020 13:42:20
Query 'Data is required. Please provide.' answered with 'While this is the first day we know about this, the AE likely started before. ' (Site from System).	(b) (4), (b) (6)	10 Sep 2020 17:20:17
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 17:19:04
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:19:04

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:19:04

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:20

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	08 Oct 2020 17:38:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	08 Oct 2020 17:39:56
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	08 Oct 2020 17:39:56
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	08 Oct 2020 17:38:48
User entered '08 Oct 2020' reason for change: New Information	(b) (4), (b) (6)	08 Oct 2020 17:38:48
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:19:04

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:20

End time (00:00-23:59)

Audit	User	Time (GMT)
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 15:22:17
Query 'Data is required. Please provide.' answered with 'not captured' (Site from System).	Xhoi Mitre (b) (4)	10 Nov 2020 21:11:43
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	08 Oct 2020 17:38:48
User entered empty.	System	10 Sep 2020 17:19:04
	(b) (4), (b) (6)	

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:20

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 17:19:04

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:20

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:20

[Death](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:20

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:20

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:19:04

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:20

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:19:04

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:20

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:19:04

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:20

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:19:04

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:20

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Related (RELATED)'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:20

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:20

[None](#)

Audit	User	Time (GMT)
User entered '1'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:20

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Oct 2020 17:39:56
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	10 Sep 2020 17:19:04

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:20

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:19:04

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:20

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 17:19:04

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:20

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Sep 2020 17:19:04

US3432094

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 26 Nov 2020 09:26:20

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	10 Sep 2020 17:19:04

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:20

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Nervous system neoplasms malignant and unspecified NEC, HLT: Nervous system neoplasms unspecified malignancy NEC, PT: Meningioma, LLT: Meningioma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 05:47:50
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	30 Oct 2020 05:47:50
Data point term sent to Coder	System	29 Oct 2020 21:06:10
User entered 'Progression of Meningioma'	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '28 Oct 2020'	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 21:05:33

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:20

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:20

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Oct 2020 21:05:33

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:20

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:20

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:20

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:20

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:20

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:20

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:20

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:20

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 03:58:28
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' answered with 'EDC is updated as per the source' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 22:42:09
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 22:41:34
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 10:00:45
User entered 'Not Applicable (NOT APPLICABLE)'	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:20

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'None (NONE)'	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:20

[None](#)

Audit	User	Time (GMT)
User entered '1'	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:20

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:20

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:20

[Narrative](#)

Audit	User	Time (GMT)
User entered empty.	Xhoi Mitre (b) (4) (b) (4)	29 Oct 2020 21:05:33

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:20

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Oct 2020 21:05:33

US3432094

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 26 Nov 2020 09:26:20

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Oct 2020 21:05:33

US3432094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:26:20

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Nervous system neoplasms malignant and unspecified NEC, HLT: Nervous system neoplasms unspecified malignancy NEC, PT: Meningioma, LLT: Meningioma - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 20:59:59
User coded data point as Term Coded data point by User: (b) (6) version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 20:59:59
Data point term sent to Coder	System	24 Nov 2020 19:36:24
User entered 'Cranioplasty and Craniectomy for Meningioma '	Monica Feeley (b) (4)	24 Nov 2020 19:35:50

US3432094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:26:20

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	24 Nov 2020 19:35:50

US3432094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:26:20

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	24 Nov 2020 19:35:50

US3432094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:26:20

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Monica Feeley (b) (4) (b) (4)	24 Nov 2020 19:35:50

US3432094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:26:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Monica Feeley (b) (4) (b) (4)	24 Nov 2020 19:35:50

US3432094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	24 Nov 2020 19:35:50

US3432094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:26:20

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 19:35:50

US3432094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:26:20

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	24 Nov 2020 19:35:50

US3432094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:26:20

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	24 Nov 2020 19:35:50

US3432094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	24 Nov 2020 19:35:50

US3432094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:26:20

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Nov 2020 19:35:50

US3432094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:26:20

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	Monica Feeley (b) (4) (b) (4)	24 Nov 2020 19:35:50

US3432094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:26:20

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Monica Feeley (b) (4) (b) (4)	24 Nov 2020 19:35:50

US3432094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:26:20

[Death](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	24 Nov 2020 19:35:50

US3432094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:26:20

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	24 Nov 2020 19:35:50

US3432094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:26:20

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'not out of hospital yet' (Site from System).	Monica Feeley (b) (4)	24 Nov 2020 19:36:04
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	24 Nov 2020 19:35:50
User entered '1'	Monica Feeley (b) (4)	24 Nov 2020 19:35:50

US3432094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:26:20

[Hospital Admission Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered '23 Nov 2020'	Monica Feeley (b) (4) (b) (4)	24 Nov 2020 19:35:50

US3432094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:26:20

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	24 Nov 2020 19:35:50

US3432094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:26:20

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	24 Nov 2020 19:35:50

US3432094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:26:20

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	24 Nov 2020 19:35:50

US3432094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:26:20

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	24 Nov 2020 19:35:50

US3432094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:26:20

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	24 Nov 2020 19:35:50

US3432094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:26:20

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	24 Nov 2020 19:35:50

US3432094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:26:20

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Monica Feeley (b) (4) (b) (4)	24 Nov 2020 19:35:50

US3432094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:26:20

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	Monica Feeley (b) (4) (b) (4)	24 Nov 2020 19:35:50

US3432094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:26:20

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	Monica Feeley (b) (4) (b) (4)	24 Nov 2020 19:35:50

US3432094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:26:20

[None](#)

Audit	User	Time (GMT)
User entered '0'	Monica Feeley (b) (4) (b) (4)	24 Nov 2020 19:35:50

US3432094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:26:20

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered '1'	Monica Feeley (b) (4) (b) (4)	24 Nov 2020 19:35:50

US3432094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:26:20

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '1'	Monica Feeley (b) (4) (b) (4)	24 Nov 2020 19:35:50

US3432094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:26:20

[Outcome](#)

Audit	User	Time (GMT)
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Monica Feeley (b) (4) (b) (4)	24 Nov 2020 19:35:50

US3432094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:26:20

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	Monica Feeley (b) (4) (b) (4)	24 Nov 2020 19:35:50

US3432094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:26:20

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Participant was admitted to the hospital on 23NOV2020 for a Cranioplasty and Craniectomy for Meningioma which is a preexisting condition.'	Monica Feeley (b) (4)	24 Nov 2020 19:35:50

US3432094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:26:20

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 19:35:50

US3432094

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 26 Nov 2020 09:26:20

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Nov 2020 19:35:50

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 26 Nov 2020 09:26:20

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:58:43

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:20

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 01:17:13
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Aug 2020 01:17:13
Data point term sent to Coder	System	11 Aug 2020 21:59:56
User entered 'Levothyroxine'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:59:38

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:59:38

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:20

[Indication](#)

Audit	User	Time (GMT)
User entered 'Pre-existing hypothyroidism'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:59:38

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:20

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '150'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:59:38

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:20

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'ug (ug)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:59:38

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:59:38

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:20

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:59:38

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:59:38

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:20

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:59:38

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:59:38

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 00:34:36
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Julia Klopfer (b) (4)	11 Aug 2020 22:14:09
answered with 'Per protocol, required' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 21:59:38
User entered 'UN UNK 1990'	Julia Klopfer (b) (4)	11 Aug 2020 21:59:38
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:59:38

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:20

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:59:38

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:59:38

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 21:59:38

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 21:59:38

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 21:59:38

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 26 Nov 2020 09:26:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 21:59:38

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:20

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 14:55:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 14:55:25
Data point term sent to Coder	System	18 Aug 2020 14:54:11
Coding entries removed.	Monica Feeley (b) (4)	18 Aug 2020 14:53:57
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 22:02:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 22:02:18
Data point term sent to Coder	System	11 Aug 2020 22:00:58
User entered 'Aspirin'	Julia Klopfer (b) (4)	11 Aug 2020 22:00:56

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:00:56

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:20

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Please use full form of CAD' (Site from CRA).	(b) (4), (b) (6)	18 Aug 2020 20:18:51
Query 'Please use full form of CAD' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	18 Aug 2020 14:54:02
User entered 'Coronary Artery Disease' reason for change: Per Query Resolution	Monica Feeley (b) (4)	18 Aug 2020 14:53:57
User opened query 'Please use full form of CAD' (Site from CRA).	(b) (4), (b) (6)	15 Aug 2020 22:58:33
User entered 'CAD'	Julia Klopfer (b) (4)	11 Aug 2020 22:00:56

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:20

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '81'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:00:56

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:20

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:00:56

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:00:56

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:20

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:00:56

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:00:56

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:20

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:00:56

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:00:56

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 07:51:10
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 00:34:40
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.' answered with 'Per protocol, required' (Site from System).	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:14:03
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	11 Aug 2020 22:00:56
User entered 'UN UNK 1990'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:00:56

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:00:56

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:20

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:00:56

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:00:56

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:00:56

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 22:00:56

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 22:00:56

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 26 Nov 2020 09:26:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 22:00:56

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:20

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: IRBESARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:04:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:04:24
Data point term sent to Coder	System	11 Aug 2020 22:03:04
User entered 'Irbesartan'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:02:52

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:02:52

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:20

[Indication](#)

Audit	User	Time (GMT)
User entered 'Hypertension'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:02:52

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:20

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '150'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:02:52

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:20

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:02:52

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:02:52

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:20

[Frequency](#)

Audit	User	Time (GMT)
User entered 'twice daily (BID)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:02:52

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:02:52

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:20

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:02:52

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:02:52

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 00:34:43
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Julia Klopfer (b) (4)	11 Aug 2020 22:13:58
answered with 'Per protocol, required' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 22:02:52
User entered 'UN UNK 1990'	Julia Klopfer (b) (4)	11 Aug 2020 22:02:52
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:02:52

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:20

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:02:52

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:02:52

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:02:52

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	11 Aug 2020 22:02:52

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 22:02:52

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 26 Nov 2020 09:26:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 22:02:52

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:20

[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: ESCITALOPRAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 22:05:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 22:05:10
Data point term sent to Coder	System	11 Aug 2020 22:04:08
User entered 'Escitalopram'	Julia Klopfer (b) (4)	11 Aug 2020 22:04:04
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:04:04

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:20

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Please mention indication on medical history.' (Site from CRA).	(b) (4), (b) (6)	26 Aug 2020 22:46:48
Query 'Please mention indication on medical history.' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	18 Aug 2020 14:58:56
User opened query 'Please mention indication on medical history.' (Site from CRA).	(b) (4)	15 Aug 2020 23:02:19
User entered 'Depression'	Julia Klopfer (b) (4)	11 Aug 2020 22:04:04

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:20

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '10'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:04:04

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:20

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:04:04

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:04:04

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:20

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:04:04

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:04:04

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:20

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:04:04

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:04:04

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 00:34:47
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Julia Klopfer (b) (4)	11 Aug 2020 22:13:51
answered with 'Per protocol, required' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 22:04:04
User entered 'UN UNK 2003'	Julia Klopfer (b) (4)	11 Aug 2020 22:04:04
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:04:04

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:20

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:04:04

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:04:04

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:04:04

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 22:04:04

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 22:04:04

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 26 Nov 2020 09:26:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 22:04:04

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:20

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 22:07:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Aug 2020 22:07:10
Data point term sent to Coder	System	11 Aug 2020 22:06:11
User entered 'Bupropion'	Julia Klopfer (b) (4)	11 Aug 2020 22:05:26

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:05:26

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:20

[Indication](#)

Audit	User	Time (GMT)
User entered 'Depression'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:05:26

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:20

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '100'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:05:26

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:20

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:05:26

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:05:26

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:20

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:05:26

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:05:26

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:20

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:05:26

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:05:26

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 00:34:50
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Julia Klopfer (b) (4)	11 Aug 2020 22:13:44
answered with 'Per protocol, required' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 22:05:26
User entered 'UN UNK 2015'	Julia Klopfer (b) (4)	11 Aug 2020 22:05:26
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:05:26

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:20

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:05:26

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:05:26

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:05:26

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 22:05:26

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 22:05:26

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 26 Nov 2020 09:26:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 22:05:26

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:20

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 14:58:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 14:58:59
Data point term sent to Coder	System	18 Aug 2020 14:57:23
Coding entries removed.	Monica Feeley (b) (4) (b) (4)	18 Aug 2020 14:56:59
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Aug 2020 22:29:08
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 Aug 2020 22:29:08
Data point term sent to Coder	System	11 Aug 2020 22:13:21
User entered 'Atorvastatin'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:12:43

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:12:43

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:20

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Please check and clarify Indication.' (Site from CRA).	(b) (4), (b) (6)	18 Aug 2020 20:19:22
Query 'Please check and clarify Indication.' answered with 'updated' (Site from CRA).	Monica Feeley (b) (4)	18 Aug 2020 14:57:04
User entered 'Coronary Artery Disease' reason for change: Per Query Resolution	Monica Feeley (b) (4)	18 Aug 2020 14:56:59
User opened query 'Please check and clarify Indication.' (Site from CRA).	(b) (4), (b) (6)	15 Aug 2020 22:56:32
User entered 'Pre-existing'	Julia Klopfer (b) (4)	11 Aug 2020 22:12:43

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:20

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:12:43

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:20

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:12:43

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:12:43

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:20

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:12:43

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:12:43

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:20

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:12:43

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:12:43

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 00:34:54
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Julia Klopfer (b) (4)	11 Aug 2020 22:13:37
answered with 'Per protocol, required' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 22:12:43
User entered 'UN Jul 2020'	Julia Klopfer (b) (4)	11 Aug 2020 22:12:43
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:12:43

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:20

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:12:43

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:12:43

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:12:43

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 22:12:43

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 22:12:43

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 26 Nov 2020 09:26:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 22:12:43

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:20

[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, PRODUCTSYNONYM: PRILOSEC [OMEPRAZOLE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:07:36
User coded data point as Term Coded data point by User: (b) (6) version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 00:07:36
Data point term sent to Coder	System	11 Aug 2020 22:13:21
User entered 'Prilosec'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:13:16

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:13:16

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:20

[Indication](#)

Audit	User	Time (GMT)
User entered 'Esophageal reflux'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:13:16

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:20

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '20'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:13:16

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:20

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:13:16

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:20

If dose unit is Other, specify

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:13:16

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:20

[Frequency](#)

Audit	User	Time (GMT)
User entered 'once daily (QD)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:13:16

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:13:16

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:20

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:13:16

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:13:16

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:20

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 00:34:58
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Julia Klopfer (b) (4)	11 Aug 2020 22:13:30
answered with 'Per protocol, required' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	11 Aug 2020 22:13:16
User entered 'UN UNK 1990'	Julia Klopfer (b) (4)	11 Aug 2020 22:13:16
	(b) (4)	

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:13:16

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:20

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:13:16

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:20

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered empty.	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:13:16

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	Julia Klopfer (b) (4) (b) (4)	11 Aug 2020 22:13:16

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 22:13:16

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Aug 2020 22:13:16

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 26 Nov 2020 09:26:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Aug 2020 22:13:16

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:20

[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: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 15:38:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Sep 2020 15:38:45
Data point term sent to Coder	System	17 Sep 2020 15:37:37
User entered 'Tylenol'	(b) (4), (b) (6)	17 Sep 2020 15:36:44

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:20

[Prophylaxis](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 15:36:44

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:20

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the SORENESS AT INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria:results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study of study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE ecrf as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of SORENESS AT INJECTION SITE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 05:02:47
User entered 'Soreness at Injection Site'	(b) (4), (b) (6)	17 Sep 2020 15:36:44

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:20

[Dose per administration](#)

Audit	User	Time (GMT)
User entered '1000'	(b) (4), (b) (6)	17 Sep 2020 15:36:44

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:20

[Dose unit](#)

Audit	User	Time (GMT)
User entered 'mg (mg)'	(b) (4), (b) (6)	17 Sep 2020 15:36:44

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:20

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 15:36:44

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:20

[Frequency](#)

Audit	User	Time (GMT)
User entered 'as needed (PRN)'	(b) (4), (b) (6)	17 Sep 2020 15:36:44

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:20

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 15:36:44

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:20

[Route of administration](#)

Audit	User	Time (GMT)
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	17 Sep 2020 15:36:44

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:20

If route of administration is Other, specify

Audit	User	Time (GMT)
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 15:36:44

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:20

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

Audit	User	Time (GMT)
User entered '10 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 15:36:44

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:20

[Start date completely unknown](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	17 Sep 2020 15:36:44

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:20

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 15:36:44

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:20

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '12 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 15:36:44

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:20

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 15:36:44

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:20

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 15:36:44

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:20

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 15:36:44

US3432094

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 26 Nov 2020 09:26:20

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Sep 2020 15:36:44